

ANALYSIS OF THE RELATIONSHIP BETWEEN PSYCHOSOCIAL FACTORS AND SELF-
EFFICACY ON SELF-MANAGEMENT BEHAVIORS
IN
ADULT PATIENTS WITH TYPE 2 DIABETES

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Dedication

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Abstract

Objectives

The nature and clinical course of diabetes, especially glycemic control, is largely influenced by patient self-management. The DAWN study underscored that fewer than 20% of patients with type 2 diabetes implement recommended self-management activities and behaviors (Funnell, 2006). Psychosocial factors, including self-efficacy, significantly influence self-management behaviors and health outcomes and have shown more influence than SES factors. This research had two major goals. One goal was to investigate the merits of a proposed integrated conceptual model for self-management to gain more insight into the complex relationships between psychosocial factors, specifically self-efficacy and the other psychosocial factors influence on self-management behaviors and A1c. Furthermore, this study sought to investigate if self-efficacy was a mediator between self-management and other psychosocial factors.

The integrated conceptual model for patient-centered self-management was proposed for study, using elements from the biopsychosocial conceptual framework; evidence-based health behavior theories; and two biomedical chronic disease self-management models. The confluence of these theoretical models is rooted in their shared emphasis on the importance of understanding the impact psychosocial factors have on self-management, and all identify *perceived self-efficacy* as a central component in self-management behavior change, especially in a chronic disease situation (Bandura, 1977). Health behaviors research of adults with type 2 diabetes

has provided evidence that individuals with improved affect, increased knowledge, more positive social support, and higher self-efficacy tend to have better self-management behaviors and clinical outcomes.

Method

This structural regression modeling study explored the direct and indirect relationships between psychosocial factors, self-efficacy, and self-management behaviors in adult patients with type 2 diabetes by evaluating a proposed conceptual model. A SEM 2 step approach was used to estimate the measurement model and the structural model. This research used cross-sectional and longitudinal data from 564 participants with suboptimal glycemic control ($A1c \geq 7\%$) from the Journey for the Control of Diabetes Interactive Dialogue to Educate and Activate (IDEA) study, a large randomized controlled trial of educational interventions for adult patients with type 2 diabetes conducted by HealthPartners Research Foundation (Sperl-Hillen, et al., 2011).

Results

The conceptual model was tested for three self-management behaviors and A1c using SEM. The model fit test statistics representing 112 parameters and 24 variables resulted in the $\chi^2 = 379$ ($df = 112$; $n=564$, $p\text{-value} = .000$). The RSMEA estimate at 0.043 (.037-.051 CI), the SRMR at 0.045, the GFI was .94. Knowledge (β 's range = .647 - .649, $p\text{ value} \leq .001$) directly and significantly influenced self-efficacy and indirectly influenced self-management significantly for the three self-management behaviors (diet, exercise and competency) and A1c (β 's range = .032 -

.253, p value $\leq .05$ and p value $\leq .001$). Diabetes social support also significantly and directly influenced knowledge ($\beta = .579$, p value $\leq .001$) and self-efficacy (β 's range = .482 - .494, p value $\leq .001$) and indirectly influenced self-management significantly for diet, exercise, competency and A1c. Affect directly influenced knowledge (β 's range = .296 - .297, p value $\leq .05$) and did not directly influence self-efficacy. Affect indirectly and significantly influenced SE (β 's range = .192 - .194, p value $\leq .05$) and self-management (β 's range = .035 - .075, p value $\leq .05$) in adults with type 2 diabetes for exercise and A1c only. A respecified conceptual model was more parsimonious through fit testing and was used throughout the research.

The research hypothesis found self-efficacy mediated self-management (Sobel test was significant at 2.41, p value of $< .05$), specifically for knowledge. SE did not mediate diabetes social support (although there was a significant direct influence on SE) or affect (no significant influence on SE). Results showed that diabetes social support, knowledge, affect did not have any direct influence, but indirectly influenced SM behaviors and A1c (with the exception of affect only significantly influenced diet and competency). During model respecification, it was discovered that knowledge also served as a mediator for DSS (Sobel test was significant at 2.454, p value of $< .014$) and was directly influenced by affect.

Conclusions

The theoretically integrated patient-centered conceptual model in this study has merit and application in self-management. The model has diabetes social support and affect retained in the model with direct links to knowledge. Knowledge is

directly linked with self-efficacy and is mediated by diabetes social support. Self-efficacy is mediating self-management. This research was designed to provide new knowledge on how psychosocial factors relate to each other and the importance of measuring self-efficacy to empower patients with a chronic disease, such as diabetes, to achieve positive self-management behavior. Improving knowledge of the relationship between psychosocial factors and self-efficacy to optimal self-management behaviors is critical to improving outcomes in diabetes care.

Keywords: Self-efficacy, Self-management behaviors, Psychosocial factors, Adult, Type 2 Diabetes, A1c, Outcomes, Structural equation modeling

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Chapter 1 - Introduction

The nature and clinical course of diabetes, especially glycemic control, is largely influenced by patient self-management behaviors (Brody, Kogan, Murry, Chen, & Brown, 2008; Daly et al., 2009; Inzucchi et al., 2012; Maddigan, Majumdar, & Johnson, 2005; Sacco et al., 2007; Williams, Freedman, Zeldman, & Deci, 2004). The International Diabetes Attitudes Wishes and Needs (DAWN) study underscored the fact that fewer than 20% of patients with diabetes mellitus type 2, hereafter referred to as patients with type 2 diabetes, implement recommended self-management activities and behaviors (Funnell, 2006). Diabetes, as a chronic disease, requires daily care and influences each part of the patient's physical, social, and psychological life. Psychosocial factors, including self-efficacy, significantly influence self-management behaviors and health outcomes (Bandura, 1977, 1997, 1998, 2004; Glasgow et al., 1989; Hartzler, Witkiewitz, Villarroel, Donovan, 2011; Nozaki et al., 2009; Sacco et al., 2007; Strecher, DeVellis, Becker, & Rosenstock, 1986; Yi, Vitaliano, Smith, Yi, & Weinger, 2008).

Despite knowledge that sustained diet and exercise behavior changes are critical to type 2 diabetes health outcomes, there are minimal studies showing the *key psychosocial mechanisms* associated with achieving significant and sustained short-term and long-term effective self-management behaviors (Inzucchi et al., 2012; National Institutes of Health [NIH], 2011). By increasing understanding of these pathways, linkages, and mechanisms, health professionals may better support the patient's role in "owning" his or her chronic condition and may align with the

patient-centered care aims recommended by the Institute of Medicine (Commonwealth Fund, 2009; Committee on Quality of Health Care in America, 2001).

Improved and positive self-management behaviors have consistently been associated directly with improved intermediate outcomes such as clinical gains (i.e., A1c reduction) and improved quality of life (QOL) in adults with type 2 diabetes (Bandura, 1998; 2004; Chiu et al., 2010; Critchley, Hardie, & Moore, 2012; Marks, Allegrante, & Lorig, 2005; Tierney et al., 2011). These improved intermediate outcomes have been directly associated with improved long-term health status outcomes (i.e., reduced morbidity and mortality).

Newly gained knowledge of the complex relationships between psychosocial factors, self-efficacy, and self-management behavior change may assist future design of more effective individualized interventions for patient and family education and indirectly improve outcomes (Bandura, 2004; West et al., 1997).

Background

The quality of diabetes care in the United States has improved over the last decade, but it is far from optimal. It is reported that 40% of American adults with diabetes still do not meet the American Diabetes Association (ADA) A1c target of less than 7% (ADA, 2011). Self-management behaviors (SMB) have been associated directly and indirectly with individual psychosocial factors and better health outcomes in adult patients with type 2 diabetes (Chiu, Wray, Beverly, &

Dominic, 2010; Nakahara et al., 2006; Nozaki et al., 2009). The need for improved chronic disease self-management behaviors is a national health care priority and will require that research studies move their focus to understanding the patient's role in health behavior change in order to address the crisis of increasing numbers of individuals with type 2 diabetes (Bodenheimer, 2007; Centers for Disease Control & Prevention [CDC], 2011) .

Diabetes mellitus is a chronic disease characterized by the body's inability to effectively use the insulin it produces, resulting in abnormally high blood glucose levels. Over 90% of people with diabetes have type 2 diabetes. In the United States alone, nearly 25 million, or 11%, of adults over age 20 are currently diagnosed with the disease or have it but do not know it (ADA, 2013). Approximately 79 million adults show evidence of impaired glucose tolerance or "pre-diabetes" (ADA, 2013). The health-care costs (direct and indirect) of diabetes care and treatment increased 41% from \$174 billion in 2007 to as much as \$245 billion in 2012, which approximates to an additional cost in medical expenditures of \$8,000 per person with diabetes (ADA, 2013; Peterson, 2008; Zhang, 2010). One in 10 health care dollars is spent treating diabetes and its complications and one in five health care dollars is spent caring for people with diabetes (ADA, 2013). Diabetes as a chronic disease is a serious national health policy issue and improving self-management is a critical component to managing related health-care costs in diabetes care.

Type 2 diabetes is a progressive disease, and if it is not controlled, serious micro- and macro-vascular complications can arise, including heart disease,

retinopathy, and kidney malfunctions. There is no known cure for the disease, and diabetes mellitus remains the seventh leading cause of morbidity and mortality listed on US death certificates (CDC, 2010). However, health can be prolonged, or complications can be prevented, by effective self-management behaviors that include lifestyle changes such as improved diet, regular exercise, self-monitored blood glucose testing (SMBG), smoking cessation, reduced alcohol use, and medication adherence (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Funnell, 2008; Norris et al., 2002).

Many of the demographic, clinical, psychosocial, and health behavioral determinants of chronic disease in general are interconnected or correlated in complex ways. It should be recognized that adult type 2 diabetes has been associated with socioeconomic indicators and genetic factors, including age, race/ethnicity, and family history (National Center for Health Statistics, 1965, CDC, 2011). Such associations make it difficult to discern the independent effects of psychosocial factors and self-efficacy on self-management behaviors. Increasing use of structural equation modeling has given researchers the ability to distinguish between direct and indirect effects among complex psychological, behavioral, and clinical relationships (Brody et al., 2008; Chiu et al., 2010; DePalma et al., 2011; Egede and Osborne, 2010; Hankonen, Vollmann, Renner, & Absetz, 2010; Nakahara et al., 2006; Osborne et al., 2010; Williams et al., 2009). Based on a review of the literature, the effect sizes of socioeconomic status (SES) factors may explain approximately 5–17% of variation in self-management behaviors. The

effect size for psychosocial factors in the literature accounts for about 15–57% of the variation in self-management behaviors, making this study worthwhile, as the ability to change psychosocial factors may be greater than influencing SES factors.

Problem Statement

Diabetes diagnoses are predicted to increase 225% between the years 2000 to 2050 in the United States due to changes in population growth, an aging population, increased populations of ethnic minorities having higher prevalence of diabetes, and demographic changes (Engelgau, 2004; CDC, 2010). Health-care systems and providers have identified the need to assist the nearly 25 million adult patients currently with type 2 diabetes, and further, to prevent the onset in the 79 million Americans who have the potential to become diabetic (ADA, 2013).

Self-management achievement is highly correlated with improved positive outcomes for diabetes care, yet remains largely unattained (Funnell, 2006; Minnesota Community Measurement Project, 2010). At the March 2010 American College of Cardiology annual meeting, disappointing five-year longitudinal medication study results from two major national diabetes-related pharmaceutical projects (ACCORD and Navigator) were shared. Researchers stated that the lack of positive findings with pharmaceutical interventions underscores the value of refocusing on self-management behaviors, including physical exercise, healthy diet, and weight loss (Winslow, 2010).

In response, the ADA and the American Association of Diabetic Educators (AADE) recently recognized that self-management is more important than initially

understood in previous research (ADA, 2010; Inzucchi et al., 2012). The AADE has defined a chronic disease management set focused on seven self-management behaviors (AADE-7), including eating healthy, being active, self-monitoring blood glucose levels, adhering to medications, solving problems, reducing risks, and using healthy coping strategies (AADE, 2010; Glasgow, 2008).

Current research shows that patients with type 2 diabetes are ultimately the final decision-makers regarding lifestyle choices, behavior, and the pharmaceutical interventions they use (Inzucchi et al., 2012). Understanding more about the relationships and effects of psychosocial factors, especially self-efficacy, may significantly improve our understanding of how self-management behavior change is attained and maintained.

Purpose of the Study

The importance of theoretical integration in health psychology research has been a recent focus in the literature (Hagger, 2009; Hagger, 2010). The adoption of more robust theoretical approaches, theoretical integration, and a focus on actual self-management behaviors with innovative study designs was recommended (Hagger, 2010). In reviewing various current theoretical and applied models and approaches to chronic disease management, specifically of patients with type 2 diabetes, there is some redundancy of constructs. Psychology, health behavioral, and biomedical disciplines each identify the mechanisms of self-management behavior differently. There is not clear agreement, as research results vary, on a consistent conceptual model of how the psychosocial factors directly and indirectly

influence self-management behaviors. Combining significant constructs from each of these three bodies of literature into one self-management conceptual model may eliminate redundancy and increase complementarity of theories in explaining self-management and ultimately, outcomes (Hagger, 2010). An innovative application of integrating multiple theoretical approaches to the study of psychosocial factors, self-efficacy, and self-management behavior would be a contribution to this area of research (Hagger, 2010).

The proposed model aims to study key psychosocial determinants that have shown significant relationships, directly and indirectly, to self-management. The importance of the role of self-efficacy as a mediator in the model was derived from the significant role it has in the studies reviewed by all three disciplines (psychology, health behavior theory, and biomedical) as discussed in the theoretical integration below.

Theoretical Integration

After an extensive review of the biopsychosocial conceptual framework (psychology), social cognitive theory (health behavior), and chronic disease management (biomedical) theoretical models and applied research pursuant to improving self-management behaviors and chronic disease outcomes, an integrated conceptual model was developed to demonstrate how psychosocial factors may directly and indirectly influence self-management (Engel, 1977; Schwartz & Weiss, 1978; Hibbard et al., 2004). The synthesis of this research was to use specific elements that were common to each model and found to be a significant

determinant of self-management to develop a proposed conceptual model for study.

The study recognizes key elements from the following theoretical foundations:

- a) The biopsychosocial conceptual framework (psychology): (Anderson, Fitzgerald, Funnell, & Gruppen, 1998; Engel, 1977; Kaplan, 1990; Schwartz & Weiss, 1978);
- b) Evidence-based health behavior theories, primarily social cognitive theory and theory of planned behavior (Bandura, 1977, 1986; DePalma, Rollison, & Camporese, 2011; Nozaki et al., 2009; Sacco et al., 2007; Tierney et al., 2011; Yi et al., 2008): and,
- c) Biomedical chronic disease self-management models, specifically the Chronic Disease Self-Management Program (CDSMP) and the Patient Activation Measure (PAM) (Marks, Allegrante, & Lorig, 2005; Hibbard et al., 2004; Hibbard, 2006).

The biopsychosocial framework substantiates how the development of comprehensive psychosocial factors, including self-efficacy, leads to self-management. The biopsychosocial framework describes how biological, psychological, and social processes are integrally involved in physical health and illness (Engel, 1997; Schwartz, 1982; Schwartz & Weiss, 1978; Suls & Rothman, 2004).

From the health behavior theories, the primary theories reviewed were social cognitive theory (SCT) (Bandura, 1977, 1985, 2000; Fernandez-Ballesteros, 2002) and theory of reasoned action and planned behavior (TPB) (Ajzen, 1985). There is a need for contribution by researchers willing to integrate the health behavior change process approach using constructs from social cognitive theory and the theory of

planned behavior (Araújo-Soares et al., 2010; Darker et al., 2010; Hankonen et al., 2010; Schwarzer, 2008). Complementary perspectives used in these two models are also found in other health behavior theories, all having elements of perceived self-efficacy, including the theory of self-determination (TSD) (Deci & Ryan, 1985); the transtheoretical model of behavior change (TBC) (Prochaska & DiClemente, 1983; DiClemente et al., 1991); and the health beliefs model (HBM) (Rosenstock, 1955; Janz & Becker, 1984).

After an extensive analysis of the biomedical chronic disease frameworks, two chronic disease management models were reviewed in detail, as they have extensive roots in the application of theory to self-management practice. The chronic disease self-management program (CDSMP) and the patient activation model (PAM) include multiple psychosocial factors in their research to improve self-management behaviors (Hibbard et al., 2004; Marks, Allegrante, & Lorig, 2005; Rosen, Schmittdiel, Hibbard, Sobel, Bellows, & Remmers, 2006).

The confluence of these three theoretical frameworks and models is rooted in their shared emphasis on the importance of understanding the impact individual psychosocial factors have on self-management. The proposed conceptual model recognizes the work from many others who have researched variation in self-management behavior through the study of affect, beliefs, knowledge, collaborative goal-setting, identification of personal barriers and supports, development of a personal action plan and individually tailored strategies, and problem solving (Glasgow et al., 2002; Lorig et al., 1999). Improved self-management behaviors

have been significantly linked to psychosocial factors, including self-efficacy, from social cognitive theory (Bodenheimer, Wagner, & Grumbach, 2002; Hibbard, Stockard, Mahoney, & Tusler, 2004; Lorig et al., 1999; and Rosen et al., 2006).

The theoretical models reviewed from all disciplines recognized the importance of individual SES and psychosocial characteristics, their social networks, and some macro system or environmental factors. All three view these as interacting and bidirectional determinants. There is agreement that the determinants are not of equal strength and may vary for different health behaviors. Among the theories, there is inconsistency in which psychosocial factors are determinants that directly and indirectly influence self-management. For example, the biomedical Patient Activation Model (PAM) did not find social support to be significant, and so it was excluded it in the final model.

In reviewing research from all three disciplines noted above, self-efficacy was consistently identified as a significant and direct predictive factor of self-management behaviors (see Figure 1). Figure 1 highlights a comparison of these theoretical disciplines findings of multiple psychosocial factors, where self-efficacy appears as a common thread among the disciplines. Within the study of self-efficacy, there are now several dimensions and defined types of self-efficacy, including perceived self-efficacy, motivational self-efficacy, and maintenance self-efficacy. For purposes of this research, *perceived self-efficacy* will be the factor used. The origin of perceived self-efficacy was from a health behavior theory, social cognitive theory, as developed by Albert Bandura (Bandura, 1977, 1985,

2000; Fernandez-Ballesteros, 2002). In this theory, Bandura outlined how human functioning is a product of a reciprocal interplay of intrapersonal, behavioral, and environmental determinants. The interaction of these three includes the exercise of self-influence, acting as an agent, as part of the causal structure an individual makes in the course of events. The relative magnitude of the human agency or personal contribution varies depending on the level of personal resources, types of activities, and situational circumstances (Bandura, 1986; 2006). Bandura describes human agency as the belief that people can exercise influence over what they do and has four properties: intentionality, forethought, self-reactiveness, and self-reflectiveness (Bandura, 2006).

Table 1

Comparison of Psychosocial Factors from Theoretical Models

<i>Theory Comparison</i>	<i>Psychosocial Factors</i>			
	<i>Affect</i>	<i>Knowledge</i>	<i>Diabetes Social Support</i>	<i>Self-efficacy</i>
<i>Biopsychosocial Framework</i>				
<i>Framework</i> (Engel, 1977)	✓	✓	✓	✓
<i>Health Behavior Theories</i>				
<i>Social Cognitive Theory</i> (Bandura, 1977)	✓	✓	✓	✓
<i>Self-Determination Theory</i> (Deci & Ryan, 1985)		✓		✓
<i>Theory of Planned Behavior</i> (Ajzen & Fishbein, 1985)	✓	✓	✓	✓
<i>Stages of Change Model</i> (Prochaska & DiClemente, 1983)	✓	✓		✓
<i>Health Beliefs Model</i> (Hochbaum, Rosenstock, &	✓		✓	

<i>Keels, 1950s)</i>				
<i>Chronic Disease Self-management Theories</i>				
<i>Chronic Disease</i>	✓	✓	✓	✓
<i>Patient Activation Model (PAM)</i>	✓	✓		✓

In social cognitive theory, perceived self-efficacy (SE) is the key factor and the foundation of human agency (Bandura, 1977). Perceived self-efficacy refers to the exercise of human agency through one's belief in their capabilities to organize and execute given types of behaviors required to produce an outcome or given attainment (Bandura, 1997). Unless people believe they can produce desired outcomes and forestall undesired ones through their actions, they have little incentive to act or to persevere in the face of difficulties, also known as "optimism bias" (Bandura, 1997; Weinstein, 1989, 1993).

Experimental manipulation of self-efficacy suggests that perceived self-efficacy can be increased, and that this enhancement is related to subsequent health behavior changes (Strecher et al., 1998). Diabetes-related perceived self-efficacy is a significant factor directly influencing self-management of adult patients with type 2 diabetes (Nakahara et al., 2006; Senecal, Nouwen, & White, 2000). Research on adults with type 2 diabetes demonstrated psychosocial factors as a key determinant directly influencing self-efficacy and indirectly influencing self-management behaviors (Nakahara et al., 2006). Perceived self-efficacy has consistently been a significant predictor of behavioral outcomes, more than any other motivation construct (Graham & Weiner, 1996). Perceived self-efficacy change has also shown

significance as a mediator between other psychosocial factors and behavior change (Bandura, 2004; Hartzler et al., 2011; Tierney et al., 2011; West, 2003). Recent research has demonstrated that baseline self-efficacy is not always a predictor of future self-management behavior change, but change in perceived self-efficacy was significantly associated with predicting the future change in outcomes such as A1c levels (Hankonen et al., 2010; Williams et al., 2009; Yi et al., 2008). A recent meta-analysis of 83 laboratory studies on conditions that may influence the relationship of self-regulation with behavioral change noted that the confidence in the findings regarding self-efficacy was limited because so few relevant studies have been conducted (Hagger, Wood, Stiff, & Chatzisarantis, 2010).

Perceived self-efficacy has been identified as a central psychosocial factor significantly related to self-management behavior change, especially in a chronic disease situation such as type 2 diabetes (Lorig et al., 1999; Bandura, 2004). Perceived self-efficacy, based on social cognitive theory, has been proven to assist people in finding ways to set and effectively pursue self-management behavior change goals. The Chapter 2 literature review describes in more detail the three theoretical frameworks and models utilized to develop the proposed conceptual model.

Proposed Conceptual Model

Current conceptual and operational chronic disease self-management models and theories are challenged by including a comprehensive set of important psychosocial factors and then reordering them. The proposed integrated self-

management conceptual model under study uniquely posits that self-efficacy acts as a *mediator* through which other key latent psychosocial factors (specifically affect, knowledge, and social support) *indirectly* influence self-management behaviors (See Figure 2). For purposes of this research, each of these psychosocial factors has large bodies of knowledge and research, and this research focused on their application within chronic diseases, especially diabetes self-management. For example, affect has many definitions, but for purposes of this research, it is defined broadly to cover a wide variety of experiences such as emotions, moods, and preferences. Concepts such as depression, distress, and attitude (positive or negative) are used as measures of affect. Affect is defined as a combination of mood and emotion. *I feel good or optimistic* is an example of a mood. In contrast, *I am angry* is an emotional state (Eysenck & Keane, 2005).

The conceptual model below proposes the direct and indirect relationships between the endogenous latent variables (diabetes social support, knowledge, affect, and self-efficacy and self-management) while controlling for exogenous variables (i.e., age, gender, and socioeconomic factors). It includes key psychosocial factors that have shown significant associations with each other and directly and indirectly with self-management. As the focus is on determining the pathways and influence of the psychosocial factors on self-management, demographic, socioeconomic, and clinical variables are included in the proposed conceptual model to control for their influence.

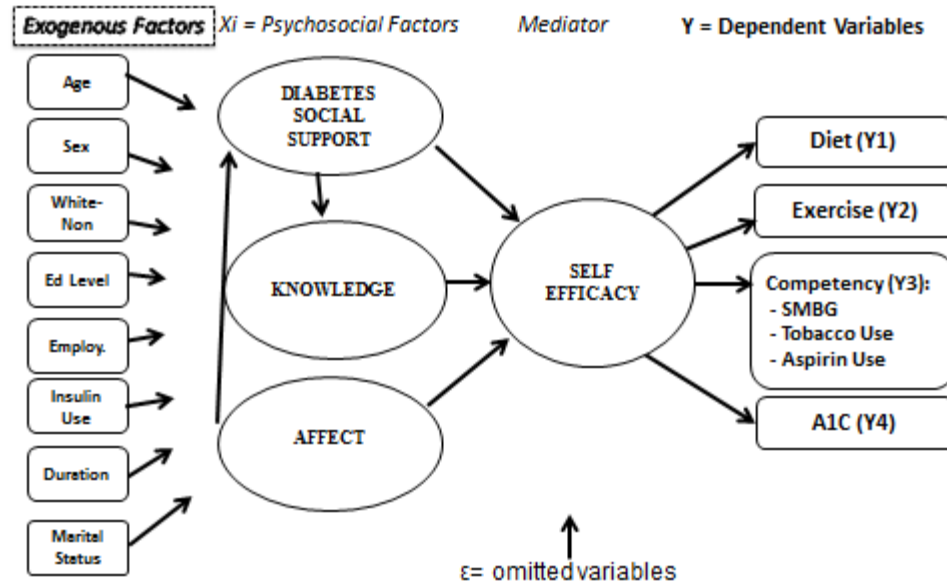


Figure 1. Self-management proposed conceptual model of psychosocial factors, self-efficacy, and self-management behaviors.

The proposed conceptual model theorizes that the latent factors of affect, knowledge, and diabetes social support directly influence self-efficacy (SE). The arrow pointing from diabetes social support to affect theorizes that diabetes social support also directly influences affect and indirectly influences self-efficacy through affect. The arrow pointing from affect directly to knowledge signifies its influence on knowledge or the ability to learn and an indirect effect on self-efficacy through knowledge. Self-efficacy was hypothesized to be the key mechanism mediating the other three psychosocial factors and self-management behaviors (SMB). SMB's are the dependent variables and are defined using three diabetes-related self-report health behaviors (diet, physical activity, and competency

regarding use of aspirin, tobacco, and SMBG testing). A1c is the fourth clinical outcome measure used in the proposed conceptual model. Exogenous demographic, socioeconomic, and clinical intensity variables measured included age, gender, ethnicity, marital status, insulin use, duration of diabetes, household income, education level, and employment status.

Research Aims

This structural regression modeling study explored the integrated conceptual model's proposed direct and indirect relationships between psychosocial factors, self-efficacy, and self-management behaviors in adult patients with type 2 diabetes. Self-management behaviors, dependent variables in this study, are studied while controlling for demographic, socioeconomic, and baseline clinical factors. The study's main research questions were as follows:

- 1) Are the psychosocial factors of affect, knowledge, and social support directly influencing self-efficacy (and therefore *indirectly* influencing self-management behaviors)?
- 2) Is self-efficacy a mediator between the psychosocial factors of affect, knowledge, and social support and self-management behaviors and A1c (and therefore *a direct* influence on self-management behavior and A1c)?
- 3) Does estimating the conceptual model between pre-educational intervention and post intervention show a significant increase in the path between knowledge and self-efficacy for those with an educational intervention (group or individual) compared to usual care.

Hypotheses. In order to address the gaps in the literature and the above aims, this research evaluated the following hypotheses:

1A) Does affect directly influence knowledge?

It was hypothesized that improved (decreased) affect would directly influence and be associated with improved (decreased) knowledge.

1B) Does social support directly influence affect?

It was hypothesized that increased (decreased) social support would directly influence and be associated with decreased (increased) affect.

1C) Do the latent psychosocial factors of affect, knowledge, and social support directly influence self-efficacy?

a. It was hypothesized that increased (decreased) affect would directly influence and be associated with decreased (increased) self-efficacy.

b. It was hypothesized that increased (decreased) knowledge would directly influence and be associated with increased (decreased) self-efficacy.

c. It was hypothesized that increased (decreased) social support factors would directly influence and be associated with increased (decreased) self-efficacy.

2) If it is shown that the psychosocial factors (affect, knowledge, and social support) directly influence self-efficacy, and if it can be shown that self-

efficacy directly influences self-management behaviors and A1c, is self-efficacy therefore acting as a mediator between psychosocial factors and self-management behaviors and A1c?

- a. It was hypothesized that affect, knowledge, and social support would not directly (but would indirectly) influence self-management behaviors and A1c.
- b. It was hypothesized that increased (decreased) self-efficacy would directly influence increased (decreased) self-management behavior(s) (food, exercise, self-care ability, and self-management competency demonstrated by SMBG testing, aspirin, and tobacco use) and A1c.
- c. It was hypothesized that self-efficacy was a direct influence on the latent factor of self-management behavior, that is, a mediator for the indirect influence of the psychosocial factors of affect, knowledge, and social support on self-management behaviors.

3) Is there a statistically significant difference in the direct path between knowledge → self-efficacy between the three randomized assigned groups: Model Group 0 (Usual Care), Model Group 1 (Individual Education), and Model Group 2 (Group Education) in T0 (baseline, pre-intervention) to T4 (twelve months, post intervention)?

- a. It was hypothesized that the knowledge to SE path Group and Individual Education groups would be statistically different (increased) from usual

care when compared at T0 (Baseline – pre-intervention) and T4 (twelve months – post intervention).

Data. Secondary data from the Journey for the Control of Diabetes

Interactive Dialogue to Educate and Activate (IDEA) study, a large randomized controlled trial of educational interventions for adult patients with type 2 diabetes conducted by HealthPartners Research Foundation, was utilized (Sperl-Hillen et al., 2011). The original study was conducted in Minnesota and New Mexico in 2008–2009 with 623 subjects with suboptimal glycemic control ($A1c \geq 7\%$). All subjects received psychosocial, self-efficacy, and self-management behavior surveys to complete over a 12-month study period. Abstracted clinical data from the electronic medical records was also included in this study.

Significance

A review of current diabetes self-management literature shows incomplete study designs and a lack of focus on the complex role of the patient as self-manager in chronic disease management. Widespread consensus across the disciplines reviewed was that a critical gap exists between the psychosocial and self-management needs of patients with type 2 diabetes and their access to effective support on these dimensions (Funnell, 2006; Inzucchi et al., 2012; Suls & Rothman, 2004; Wroe, 2006). A literature gap exists in studies that examine a comprehensive set of psychosocial factors and interactions of these complex factors related to self-management behaviors (DePalma et al., 2011). Few prospective or longitudinal studies have examined the relationship between a comprehensive set of

psychosocial factors, self-efficacy, and self-management behaviors (Nozaki et al., 2009). The research studies that examine various components of psychosocial factors and their relationships to self-management behaviors have produced important findings (Brody et al., 2008; Daly et al., 2009; DePalma et al., 2011; Egede & Osborne, 2010; Hartzler et al., 2011; Nakahara et al., 2006; Nozaki et al., 2009; Williams et al., 2005, 2009; Yi et al., 2008).

The significance of this research was to provide new knowledge regarding gaps in our current understanding of the complex mechanisms and underlying pathways between psychosocial factors, self-efficacy, and self-management behaviors as they influence adult patients with type 2 diabetes (Bandura, 1997, 2004; Osborne, Bains, & Egede, 2010; Tierney et al., 2011).

Developing a unique and integrated biopsychosocial, behavioral health, and biomedical integrated self-management conceptual model may allow for more understanding of how complex systems interact in chronic disease self-management. Increased knowledge of the strength and direction of multiple psychosocial factors that may influence or predict self-management behaviors over time may further assist patients and health-care professionals in their quest to prevent diabetes and improve outcomes. Examining self-efficacy as a possible mediator between other psychosocial factors in predicting self-management behaviors could be a significant contribution to better understanding the mechanism that controls how psychosocial factors influence self-management. The findings from this study may enhance our understanding of static and temporal associations

between a more complete set of psychosocial factors and self-management behaviors (Lippa, Klein, & Shalin, 2008).

Increasing the effectiveness of health-care professionals' role in chronic disease management, patient education, and care interventions for adult patients with type 2 diabetes is critical to improving self-management in diabetes care (Tierney et al., 2011). Ultimately, improved chronic disease self-management improves clinical and quality of life outcomes. Increasing understanding of self-management behaviors in patients with type 2 diabetes is of critical value to the health of our nation's population. The clear lack of evidence in effective self-management among patients with type 2 diabetes warrants moving forward with this timely research.

Key Terms

A1c: The A1c test measures average blood glucose control for the past 2 to 3 months. It is determined by measuring the percentage of glycated hemoglobin, or HbA1c, in the blood (ADA, 2013).

Affect: The latent construct of affect in this research refers to the mood and emotional state of an individual. Emotions include anxiety, anger, distress, guilt, and depression.

Biopsychosocial factors: Biological, psychological and social factors all play a significant role in human functioning in the context of disease or illness.

Biopsychosocial conceptual framework (psychology): This framework describes how biological, psychological, and social processes are integrally involved in physical health and illness (Engel, 1997; Schwartz, 1982; Schwartz & Weiss, 1978; Suls & Rothman, 2004).

Chronic Disease Self-management Program: This program is highly studied and utilizes an interventional self-management model that has documented improved health status and decreased utilization of health-care resources in chronic disease

management (Lorig et al., 1999). This model uses social cognitive theory, particularly the influence of improved self-efficacy, to improve health behaviors. It also incorporates a) focus on skill building for problem solving and decision making; b) reinterpretation of symptoms; and c) social persuasion.

Exogenous variables: Independent variable that affects a model without being affected by it, and whose qualitative characteristics and method of generation are not specified by the model builder. An exogenous variable is used for setting arbitrary external conditions.

Health literacy: Is defined as “the degree to which individuals have the capacity (skills and abilities) to obtain, process, and understand basic health information and navigate health services needed to make appropriate health decisions . . .” (Ad Hoc Committee on Health Literacy, 1999; Baker, 2006).

Integrated conceptual model: The synthesis of various research models using specific elements that were common from each and/or found to be significant determinants of self-management to develop a proposed conceptual model for study. In this study, an integrated conceptual model demonstrates how psychosocial factors may directly and indirectly influence self-management.

Knowledge: The theoretical or practical understanding of a subject, in this case type 2 diabetes. Knowledge is the understanding of diabetes as a disease, knowing the general principles of its treatment, and identifying skills needed for self-management (Beeney, Steward, & Welch, 2003). Knowledge is also one of three latent variables (affect, knowledge, and social support) directly influencing self-efficacy.

Latent construct: Latent constructs are theoretical in nature; they cannot be observed directly and, therefore, cannot be measured directly either. To measure a latent construct, researchers capture indicators that represent the underlying construct. The indicators are directly observable and believed by the researcher to accurately represent the variable that cannot be observed. Byrne (1998) says it well: “. . . the researcher must operationally define the latent variable of interest in terms of behavior believed to represent it. As such, the unobserved variable is linked to one that is observable, thereby making its measurement possible.” (p. 4)

Latent factors: In statistics, latent factors (as opposed to observed variables) are variables that are not directly observed but are rather inferred (through a mathematical model) from other observed variables that are directly measured.

Mediation: As used in this research, a mediator is a variable that accounts for the relation between the predictor and criterion. This relationship can be tested

optimally with structural equation modeling (SEM) techniques using a series of nested models.

Observed variable (indicators): A variable that can be observed or measured.

Patient activation measure: With the more recent focus on the importance of the patient as self-manager in the medical chronic disease management literature, a patient activation model has shown significance using psychosocial factors to predict self-management and improved outcomes (Hibbard et al., 2004; Rosen et al., 2006).

Perceived self-efficacy: The exercise of human agency is through one's belief in one's capabilities to organize and execute given types of behaviors required to produce an outcome or given attainment. Perceived self-efficacy has been identified as a central psychosocial factor significantly related to self-management behavior change, especially in a chronic disease situation (Bandura, 2004).

Psychosocial factors: Psychosocial factors are those factors that affect a person psychologically or socially and influence the ability to manage daily functions.

Self-efficacy: The belief that one can achieve what one sets out to do (Bandura, 1977). Self-efficacy is believed to be the single most important characteristic that determines a person's behavior change (Grizzell, 2007).

Self-management behaviors: Self-management behavior (SMB) is defined as any action that a patient engages in that is seen as health promoting and that a health-care clinician could recommend (Sackett & Haynes, 1979; Lorig et al., 2002). Self-management is what the person with a chronic disease does to manage his or her own illness, not what the health clinician does. It includes healthy lifestyle choices, informed decisions regarding ongoing treatment options that fit within the person's broader social context, and actively monitoring and managing symptoms.

Social cognitive theory: This theory is the concept of perceived self-efficacy, involving a judgment of one's abilities in the realm of attainment and motivation (Bandura, 1977, 1985, 2000; Fernandez-Ballesteros, 2002). Social cognitive theory proposes that health behavior is influenced by environmental influences, personal factors, and attributes of the behavior itself. SCT specifies a set of core determinants including 1) *knowledge* of health risks and benefits of different health practices, 2) *perceived self-efficacy* that one can exercise control over one's health habits, 3) *outcome expectations* about the expected costs and benefits for different health habits, 4) the health *goals* people set for themselves and the concrete plans and strategies for realizing them, and 5) the *perceived facilitators* and social and structural *impediments* to the changes they seek (Bandura, 2004).

Social support: Social support is a concept researchers have used to understand the impact of interpersonal relationships on chronic disease management (Kronish & Mann, 2010). Relationships and affiliations have powerful effects on physical and mental health.

Structural equation modeling: Structural equation modeling (SEM) is a statistical technique for testing and estimating causal relations using a combination of statistical data and qualitative causal assumptions. Among the strengths of SEM is the ability to construct latent variables - variables that are not measured directly but are estimated in the model from several measured or observed variables, each of which is predicted to “tap into” the latent variables. This allows the modeler to explicitly capture the unreliability of measurement in the model, which in theory allows the structural relations between latent variables to be accurately estimated.

Theoretical integration: Theoretical integration is characterized by openness to various ways of integrating diverse theories and techniques, or in this case, creating a proposed conceptual model.

Theory of planned behavior: An updated theoretical framework for behavioral achievement that involves three antecedents to motivation and achievement: attitudes toward the behavior, subjective norms, and perceived behavior control (self-efficacy). Originally in the theory of reasoned action, behavioral achievement was believed to depend jointly on only motivation [intention] and ability [behavioral control] [Ajzen, 1991]. After research in behavior achievement, this theory was updated and renamed the “theory of planned behavior.”)

Theory of self-determination (Deci & Ryan, 1985): highlights the use of motivation, the area of psychology that has particular relevance to the issue of self-management activities. Motivation encompasses self-regulatory processes involving the selection, activation, and sustained direction of behavior toward certain goals. Self-determination theory research has shown that the two factors of autonomous (versus controlled) motivation and competence (versus incompetence) motivation correlate with improved glycemic control.

Transtheoretical model of behavior change (TBC) (Prochaska, & DiClemente, 1983; DiClemente et al., 1991): In 1983, Prochaska and DiClemente proposed the Stages of Change (SOC) behavior change model that conceptualized a five-stage process related to a person’s readiness to change: pre-contemplation, contemplation, preparation, action, and maintenance. SOC theory suggests that because individuals’ outcome expectations and self-efficacy levels vary, depending upon the state of change they are in, unique interventions—tailored to these states—were needed to move the individuals forward effectively through the stages of change (Bandura, 1986).

Chapter 2 - Review of the Literature

Multiple theoretical frameworks, theories, and models are used to describe the mechanisms surrounding health behaviors and self-management in patients with chronic disease. This literature review focused on better understanding the influence of psychosocial factors, including self-efficacy, on self-management in adult patients with type 2 diabetes. A review with more details of the relevant literature from the psychological, biomedical, and biobehavioral disciplines follows. Aspects of the biopsychosocial health behavior framework (Engel, 1997; Schwartz & Weiss, 1978; Suls & Rothman, 2004), the chronic disease model of Patient Activation Measure (PAM) (Hibbard et al., 2004), and selected health behavior theories that influenced the development of the proposed conceptual model (Araújo-Soares et al., 2009; Bandura, 1977; Darker et al., 2009; Hagger, 2009; Hagger, 2010) are included.

The “biopsychosocial model” from health psychology outlines how biological, psychological, and social processes are interlinked and interactively involved in an individual’s physical health and illness (Engel, 1977; Schwartz & Weiss, 1978; Suls & Rothman, 2004). Schwartz noted in his description of the biopsychosocial approach:

To the extent the biopsychosocial approach more effectively stimulates *common* theories and research designs, facilitates *interdisciplinary* thinking and research, and encourages greater *synthesis* among *numerous* variables, it has the potential to establish a more effective, multi-cause, multi-effect approach to health and illness. (Schwartz, 1982, p. 1049)

This framework asserts that a medical (clinical) diagnosis, in this case type 2 diabetes, that takes into consideration the interaction of biological, psychological, and social factors should lead to better treatment and outcomes (Glasgow, 2004).

The second theoretical models that influenced the proposed conceptual model were from multiple health behaviors research. Research on the application of these theories to adults with type 2 diabetes has provided evidence that individuals with improved affect, increased knowledge, more positive social support, and higher self-efficacy have better self-management behaviors and clinical outcomes (Bandura, 1998, 2004; Chiu et al., 2010; Critchley, Hardie, & Moore, 2012; Tierney et al., 2011). Health behaviors research includes the key element of perceived self-efficacy from social-cognitive theory (Bandura, 1977). Self-efficacy involves a judgment of one's abilities in the realm of attainment and motivation (Bandura, 1977). Other health behavior theories also emphasize the influence of perceptions of control over behavior, utilizing labels such as self-efficacy (health belief model, social cognitive theory) and perceived behavioral control (theory of planned behavior). The theory of planned behavior (TPB) incorporated Bandura's work from social cognition theory into its model by including perceived self-efficacy (perceived behavior control) (Ajzen, 1985).

The third section of this review focused on the psychosocial factors that were validated using biomedical chronic disease research models for diabetes—specifically the Chronic Disease Self-Management Program (CDSMP) and the Patient Activation Measure (PAM) (Lorig, 2003; Marks, Allegrante, & Lorig, 2005;

Hibbard et al., 2004). These models focus on the importance of psychosocial factors in the achievement of self-management behaviors and improved outcomes in chronic disease management (NICE, 2008).

Biopsychosocial Theoretical Framework

The biopsychosocial framework describes how biological, psychological, and social processes are integrally and interactively involved in physical health and illness (Engel, 1997; Schwartz, 1982; Schwartz & Weiss, 1978; Suls & Rothman, 2004). Self-management is depicted as directly influencing both clinical and quality of life outcomes. The framework maintains that individual, social, and environmental factors directly and indirectly influence outcomes through self-management, and that all relationships are reciprocal.

Within the individual factors, several psychosocial, demographic, and socioeconomic factors influencing self-management were specified. Key examples of individual factors included in the biopsychosocial framework include affect, coping abilities, distress, personality, age, and gender. Self-efficacy was also noted as an important individual psychosocial factor. Multiple social factors were theorized to be important, including social support, family character, impact on partner, number in household, socioeconomic status, ethnicity, and health-care provider.

The biopsychosocial framework category for environmental included factors such as the health-care system, access, incentives for exercise and diet, work/school environment, community programs, neighborhood, cultural factors, and media. The

worksite, for example, may present challenges, like finding time and privacy to monitor blood glucose, inject insulin, or eat at times when symptoms call for a snack (Trief, Aquilino, Paradies, & Weinstock, 1999; Wood & Jacobson, 2008).

The proposed conceptual model utilized key elements from the biopsychosocial theory as a primary framework (Suls & Rothman, 2004; Engel, 1977; Schwartz & Weiss, 1978). The influence of the biopsychosocial framework on this study's proposed self-management conceptual model included the following: individual psychosocial factors of affect including distress, self-efficacy, coping abilities, personality, age, and gender; social framework factors of social support, family character, impact on partner, number in household, and SES/ethnicity; and environment self-management behaviors of diet, exercise, self-testing, daily decision making, and medications. Outcome measures were not included in this study and could be considered in a future research model.

Figure 2 below highlights those factors from the biopsychosocial framework that were included in the development of the integrated conceptual model under study and those factors that were not directly included. A meta-analysis conducted at the tenth anniversary of the introduction of the biopsychosocial model found less than 36% of researchers were studying all components of the model (Suls & Rothman, 2004).

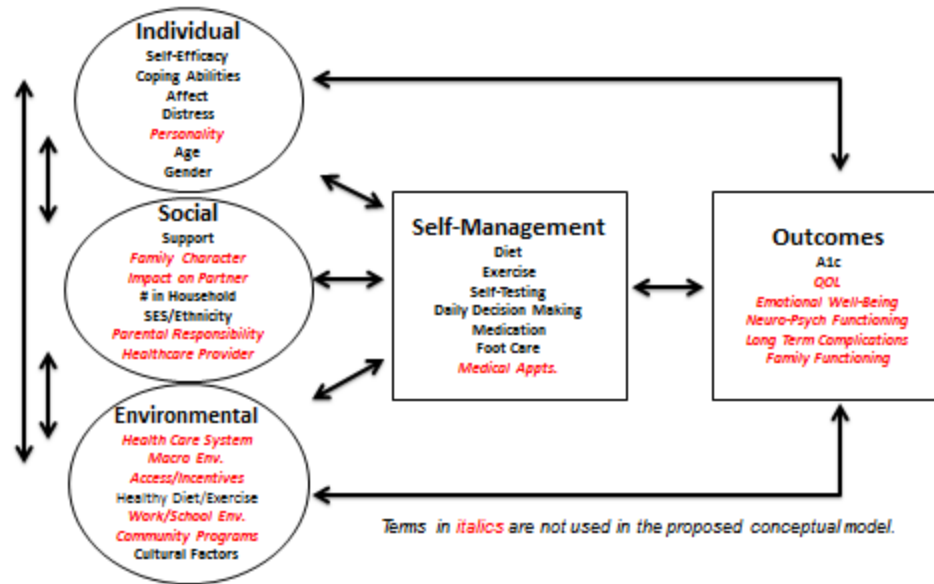


Figure 2. Biopsychosocial theoretical conceptual framework as modified for this study.

The biopsychosocial framework substantiated the development of a model using comprehensive psychosocial factors leading to self-management. The biopsychosocial factors of focus included in this research are individual and social, with an emphasis on the individual role of self-efficacy as a mediating psychosocial factor. To focus this study, several known baseline environmental factors, including SES and clinical factors, were controlled. Quality of life outcomes, despite knowledge that links direct correlations between self-management behavior and quality of life and clinical outcomes have been excluded from the conceptual model at this time.

Health-Related Behavioral Theoretical Framework

While the biopsychosocial theoretical framework identifies linkages in multiple systems of biological, psychological, and social processes as they interact with self-management behaviors and outcomes, the upcoming health behavior theories highlight the role of perceived self-efficacy, perceived benefits and barriers, and the role of outcome expectations that influence self-management behaviors and outcomes. Most of the health-behavior theoretical frameworks outlined below emphasize self-efficacy's influence on self-management, leading to more effective approaches to care and better outcomes.

The primary health behavior theories utilized to develop the proposed integrated conceptual model included social cognitive theory (SCT) (Bandura, 1977, 1985, 2000; Fernandez-Ballesteros, 2002) and theory of reasoned action and planned behavior (TPB) (Ajzen, 1985). Some relevance was found in several other theories: the theory of self-determination (TSD) (Deci, & Ryan, 1985); the transtheoretical model of behavior change (TBC) (Prochaska & DiClemente, 1983; DiClemente et al., 1991); and the health beliefs model (HBM) (Janz & Becker, 1984).

Of the multiple chronic disease self-management biomedical models explored with some relevance to the proposed conceptual model, the chronic disease self-management model (Daly et al., 2009; Lorig, 1993; Glasgow, 1994) and the patient activation measure (PAM) developed by Hibbard and her team

(Hibbard et al., 2004; Rosen et al., 2006) were utilized. More detail on all of these theories is included in the following sections.

Similarities between the behavioral and social science theories and models have been used to understand and enhance self-management behaviors in patients with type 2 diabetes. Many studies focused on the need to eat a healthy diet and increase physical activity. Several health behavior theoretical approaches highlight the role of the perceived outcomes of behavior, although different terms are used for this construct, including perceived benefits and barriers (health belief model), and outcome expectations (social cognitive theory and theory of planned behavior). These theories emphasize the influence of an individual's perception of control over behavior; this influence has been given labels such as perceived self-efficacy (social cognitive theory and health belief model) and perceived behavioral control (theory of planned behavior). The role of social or interpersonal influences, as in the concepts of observational learning (social cognitive theory), and perceived norm (theory of reasoned action and theory of planned behavior), and interpersonal influences have been noted as important. Yet, because the confidence (or lack thereof) that an individual has in his or her ability to perform self-management behaviors is so important, self-efficacy is believed to be the single most important characteristic that determines a person's behavior change (Grizzell, 2007).

Social cognitive theory and the theory of planned behavior are two key health behavior theories that have continued to demonstrate pertinence to enhanced understanding of what influences the achievement of self-management behavior in

patients with type 2 diabetes. These health behavior theories and other related theories are described in more detail in the next section.

Social-cognitive theory. Social-cognitive theory (SCT) was proposed by Bandura to better understand human motivation, and has been utilized with significance in the literature surrounding human health behaviors, including diabetes-related behaviors (Bandura, 1977, 1986; DePalma et al., 2011; Nozaki et al., 2009; Sacco et al., 2007; Tierney et al., 2011; Yi et al., 2008). Social cognitive theory proposes that health behavior is impacted by environmental influences, personal factors, and attributes of the behavior itself. SCT specifies a set of core determinants including: 1) knowledge of health risks and benefits of different health practices, 2) perceived self-efficacy that one can exercise control over one's health habits, 3) outcome expectations about the expected costs and benefits for different health habits, 4) the health goals people set for themselves and the concrete plans and strategies for realizing them, and 5) the perceived facilitators and social and structural impediments to the changes they seek (Bandura, 2004).

The key element of social-cognitive theory is the concept of perceived self-efficacy, which involves a judgment of one's abilities in the realm of attainment and motivation (Bandura, 1977). A person must believe in his or her capability of performing the behavior (self-efficacy) and must perceive an incentive to do so (positive expectations outweigh negative expectations). According to Bandura, perceived self-efficacy contributes to motivation in several ways: (a) by shaping aspirations and goals (Campion & Lord, 1982); (b) by determining the amount of

effort and perseverance one will expend in a given endeavor; and (c) by shaping the outcomes expected from one's efforts (Bandura, 1986, 1997). People who perceive themselves as highly efficacious will expect favorable outcomes, whereas those with less confidence in their performance capabilities will envision negative outcomes. In addition, progressive mastery of a given activity leads to satisfaction, which in turn serves as an ongoing motivator and increases self-efficacy (Bandura & Schunk, 1981).

Theory of planned behavior. The theory of planned behavior is an extension of the theory of reasoned action made necessary by the original model's limitations in explaining behaviors over which people have incomplete volitional control (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975). Originally, in the theory of reasoned action, behavioral achievement was believed to depend jointly on only motivation (intention) and ability (behavioral control) (Ajzen, 1991). After research in behavior achievement, this theory was updated and renamed the "theory of planned behavior" (TPB). It incorporated findings from Bandura's social cognitive theory into its model, specifically by including self-efficacy or perceived behavior control (Ajzen, 1985). This updated theoretical framework for behavioral achievement now involved three antecedents to motivation and achievement: attitudes toward the behavior, subjective norms, and perceived behavior control (self-efficacy).

As in the original theory of reasoned action, a central factor in the theory of planned behavior is the individual's *intention* to perform a given behavior (Ajzen,

1991). Intentions are assumed to capture the motivational factors that influence a behavior. They are indications of how much of an effort an individual plans to exert to perform the behavior. Generally, the stronger the intention to engage in a behavior, the more likely it will be performed. Behavioral intention can find expression in behavior only if the behavior in question is under volitional control, that is, the person can decide at will to perform or not perform the behavior.

Although some behaviors may meet this requirement quite well, the performance of most behaviors depends at least to some degree on nonmotivational factors such as availability of requisite opportunities and resources (e.g., time, money, skills, and/or cooperation of others) (Ajzen, 1985). Collectively, these factors represent people's *actual* control over the behavior. To the extent that a person has the required opportunities and resources and intends to perform the behavior, he or she is predicted to succeed in doing so.

Intentions to perform behaviors of different kinds can be predicted with high accuracy from attitudes toward the behavior, subjective norms, and perceived behavioral control (perceived self-efficacy). These intentions, together with perceived self-efficacy, account for considerable variance in actual behavior (Ajzen, 1985). Attitudes, subjective norms, and perceived behavioral control have been shown to be related to appropriate sets of salient behavioral, normative, and control beliefs about the behavior, but the exact nature of these relations is still uncertain (Ajzen, 1985).

Additional research with the TPB model showed that perceived behavior control (self-efficacy) is independently a significant predictor of behavioral achievement in weight control, alcohol use, attending class, and cognitive task performance, without having to go “through intention,” as originally theorized (Ajzen, 1985). TPB research supports the use of perceived self-efficacy as an underlying mechanism in achievement of self-management behavior change.

Self-determination theory. The self-determination theory (SDT) highlights the use of motivation. Motivation is the area of psychology that has particular relevance to the issue of self-management activities (Ryan and Deci, 2000; Williams & Zeldman, 2002; Williams et al., 2004). Motivation encompasses self-regulatory processes involving the selection, activation, and sustained direction of behavior toward certain goals (Bandura, 1997). SDT research has shown that the two factors of autonomous (versus controlled) motivation and competence (versus incompetence) motivation correlate with improved glycemic control (Senecal et al., 2000; Williams et al., 2009).

A SDT research study reported that patients in a randomized, longitudinal study of glycemic control who were rated as more actively involved in discussions of diabetes self-management, compared to those rated as passive, were more likely to experience improvement in glycemic control. A patient activation intervention increased directly the active involvement of patients with type 2 diabetes in visits with practitioners, which was significantly associated with improved glycemic control (A1c). The patient activation intervention was not found to increase

competence motivation (self-efficacy) or promote the internalization of motivation for diabetes self-management. Finally, the patient activation intervention did not directly, but did indirectly; improve glycemic control (Williams et al., 2005). This theory supports the conceptualization of self-efficacy as a mediator between other psychosocial factors and self-management.

Transtheoretical (stages of change) model. In 1983, Prochaska and DiClemente proposed the Stages of Change (SOC) behavior change model that conceptualized a five-stage process related to a person's readiness to change: pre-contemplation, contemplation, preparation, action, and maintenance. The major psychological factors hypothesized to move an individual through the stages of change are similar to those in social cognitive theory, including self-efficacy (Bandura, 1986). SOC theory suggests that because individuals' outcome expectations and self-efficacy levels vary, depending upon the state of change they are in, unique interventions—tailored to these states—were needed to move the individuals forward effectively through the stages of change (Prochaska et al., 1994). Thus, readiness to change and self-efficacy again showed a significant role in this transtheoretical approach to describing health behavior. This is similar to the importance of knowledge in self-management behavior as described in the biopsychosocial framework.

Health belief model. The Health Belief Model (HBM) is a psychological model designed to explain and predict health behaviors by focusing on the attitudes and beliefs of individuals. Three social psychologists, Hochbaum, Rosenstock, and

Kegels, developed this theory in the 1950s. The HBM theory utilizes a person's perception of four key areas: severity of a potential illness, their susceptibility to the illness, their belief of the benefits of taking a preventive action, and the barriers to taking that action (Janz & Becker, 1984). After extensive research, the Health Beliefs Model was updated in 1988 to include self-efficacy, defined as one's confidence in one's ability to successfully perform an action (Rosenstock, 1988; Center for Health Communications Research, 2009). The HBM core assumptions include the following: a) an understanding that a person will take a health-related action if that person feels that the negative health event can be avoided; b) a positive expectation that by taking a recommended action he/she will avoid a negative health issue; and c) a belief that he/she can successfully take a recommended health action (self-efficacy).

The diabetes-specific instrument, Diabetes Care Profile (DCP), was developed to measure each of the four major constructs of the HBM model: perceived severity of the disease, perceived susceptibility to complications, benefits of self-management behaviors, and barriers to self-management behaviors (Fitzgerald et al., 1986).

Subsequent studies reported relationships between self-management behaviors and belief in the severity of the illness and a diabetes belief scale (Harris & Linn, 1985). The health beliefs of patients with diabetes (self-efficacy) accounted for 41%–50% of variance in patients' reported self-management (Harris & Linn, 1998; Wilson & Endres, 1986).

Biomedical Chronic Disease Self-management Framework

An underlying theme of the more current medical (biomedical) chronic disease self-management perspective is that the most effective interventions occur on multiple levels. In the literature, self-management is often referred to as “adherence or compliance,” as reflected in the biomedical realm of research with chronic diseases. Two significant models, the Chronic Disease Self-Management Program (CDSMP) and the Patient Activation Measure (PAM), have produced real improvements and results in improving chronic disease clinical and quality of life outcomes, are discussed further in the next section (Hibbard et al., 2004; Lorig, 2003; Marks, Allegrante, Lorig, 2005; Rosen et al., 2006).

Chronic disease self-management program. The Chronic Disease Self-Management Program is one highly studied and utilized interventional self-management model that has documented improved health status and decreased utilization of health-care resources in chronic disease management (Lorig et al., 1999). This model uses social cognitive theory, particularly the influence of improved self-efficacy, to improve health behaviors. It also incorporates a) a focus on skill building for problem solving and decision making; b) reinterpretation of symptoms; and c) social persuasion (Marks, Allegrante, & Lorig, 2005). This intervention model has been applied to multiple types of chronic diseases with outcomes success, including improved self-efficacy and diet and exercise self-management in adult patients with diabetes. Interventions that simultaneously influence multiple levels and multiple settings have shown the ability to lead to

greater and longer-lasting changes and maintenance of existing self-management habits (Grizzell, 2007).

Patient activation measure. A second chronic disease self-management model reviewed in this research was the patient activation model, commonly referred to as PAM (Hibbard et al., 2004; Rosen et al., 2006).

With the more recent focus on the importance of the patient as self-manager in the medical chronic disease management literature, a patient activation model has shown significance using psychosocial factors to predict self-management and improved outcomes (Hibbard et al., 2004; Rosen et al., 2006). This model developed a Patient Activation Measure (PAM) using multiple psychosocial factors, including affect, cognition, and self-management behavioral dimensions as important to achieving effective chronic disease management in patients with type 2 diabetes. The PAM described four stages of patient activation: (1) believing the patient role is important, (2) having the confidence (self-efficacy) and knowledge necessary to take action (knowledge), (3) actually taking action to maintain and improve one's health (self-management), and (4) staying the course even under stress (affect) (Hibbard et al., 2004). A social factor was removed from the original model after initial psychometric testing did not show significance in the final predictive model of the PAM measure when studied with patients with diabetes and other chronic diseases (Hibbard et al., 2004). A heuristic model for teaching self-management support to health-care providers was then designed from this research. Subsequent studies have shown that engagement and activation of patients,

measured by the PAM, were significant predictors of positive self-management behaviors and health-related quality of life (QOL) performance results of chronic disease patients, including adult patients with diabetes (Hibbard et al., 2004; Rosen et al., 2006).

Theoretical Integration

After reviewing the three research-based frameworks outlined above, health psychology (biopsychosocial framework), health behavioral theory (social cognitive theory), and biomedical (Chronic Disease Self-Management Program and Patient Activation), all intersect in their belief in the important and complex role multiple psychosocial factors, especially self-efficacy; have in chronic disease self-management (Bandura, 2004; Marks, Allegrante, & Lorig, 2005).

Self-management training that focuses on increasing perceived self-efficacy consistently shows enduring outcomes, including reduced pain, slower biological disease progression, and reduced physician visits over time (Holman & Lorig, 1992). Baseline self-efficacy beliefs and changes in efficacy beliefs to exercise some control over one's chronic condition explain level of pain years later (Lorig, 1990). Tests of alternative mediating mechanisms other than self-efficacy reveal that increases neither in knowledge nor in the degree of change in health behaviors are good predictors of health functioning (Lorig, Chastain, Ung, Shoor, & Holman, 1989; Lorig et al., 1989). The belief that one can exercise some control over one's psychosocial functioning and strive to improve quality of life, perceived self-efficacy, has been shown to account for a major share of the variation to self-

management in those living with a chronic disease (Cunningham, Lockwood, & Cunningham, 1991).

There is still inconsistency among these frameworks, although common factors are emerging for inclusion in a comprehensive model. For example, PAM used multiple psychosocial factors, but through its measurement tool based on its research, excluded social support. However, many other important chronic disease management studies continue to show significance with social support. All three disciplines have acknowledged perceived self-efficacy, affect, and knowledge as significant psychosocial factors in determining self-management. It is clear that perceived psychosocial factors, especially self-efficacy, play a central role.

The following, more detailed, literature review shares more information on the important individual psychosocial factors of affect, knowledge and social support, self-efficacy, and their impact on key self-management behaviors for adult patients with type 2 diabetes. A review of the literature on the demographic, socioeconomic, and baseline clinical intensity exogenous variables utilized in this research follows in the next sections.

Psychosocial Factors

The influence of psychosocial factors, including self-efficacy, on self-management behaviors has been studied extensively, with mixed results indicating direct and indirect associations between these factors. Behavioral health (psychology) research in the 1970s addressed the integration of the individual, social, and environmental factors, as discussed previously. Expanded research on

chronic disease management was focused on applying health behavior theory to self-management. Research in the 1990's began to add value to the treatment of diabetes with a new focus on the impact of behavioral change, social networks, affective needs, spiritual beliefs, and cognitive processes on self-management (Hagan, Moriarty, Zack, Scherr, & Brackbill, 1994). The medical chronic disease management literature acknowledged several significant psychosocial factors, including affect, cognition, and behavioral and physiological dimensions as important to achieving effective chronic disease management in patients with type 2 diabetes. Health behavior theories focused on self-efficacy's role in health behavior change, along with the patient's readiness to change.

Chronic disease diabetes studies have shown that individual interventions have the ability to improve exercise and diet behaviors. These key behaviors have been associated with mood and knowledge as important significant psychosocial variables (Critchley, Hardie, & Moore, 2012; Weinstein, Deuster, & Francis, 2010). The following sections describe in more detail the pertinent literature for each of the key psychosocial factors (affect, knowledge, and social) under research.

Affect. Affect describes a set of mood and emotional states of an individual. Patients diagnosed with type 2 diabetes often experience a range of emotions, including anxiety, anger, guilt, and sadness, which may negatively influence their ability to learn and practice self-management skills (ADA, 2007). Diabetes requires a high level of self-management behavior. Anxiety and stress have been linked to negative glycemic control (Sultan, Epel, Sachon, Vaillant, & Hartemann-Heurtier,

2008). Research on interventions with adult patients with diabetes demonstrated that increased knowledge and mood were associated with an increase in physical activity (Critchley et al., 2012). The three aspects measured to define affect in this research included depression, anxiety or distress, and positive/negative attitude. These concepts are reviewed in more detail in the following sections.

Depression. Multiple studies have documented that depression is significantly higher among persons with diabetes relative to the general population, which has an overall rate of 6.7% (Ali et al., 2006; Anderson, Fitzgerald, Funnell, Gruppen, & Oh, 2003; Egede, 2007; Wexler et al., 2006). Depression or negative mood affects approximately 15 to 30% of adults with diabetes as a comorbid symptom, and approximately 10% of those suffer major depression (Anderson et al., 2001; Egede & Simpson, 2003). Stressful life events can also cause negative mood or depression, and have been strongly associated with poor glycemic (A1c) control (Katon et al., 2004; Lustman et al., 2000; Richardson et al., 2008; Yi et al., 2008).

Depression, a common indicator of psychological distress in adults, has been associated with metabolic control (Lustman, Freeland, Griffith, & Clouse, 2000). There is still a lack of clear understanding of how depression is associated with poor glycemic control. Depression has been theorized to be physiologically related to metabolic control or to affect it indirectly by decreasing self-management behaviors (Helgeson, Siminerio, Escobar, & Becker, 2009). Prior studies have shown that depression has a direct effect on self-management behaviors and an

indirect effect on A1c (Chiu et al., 2010; Egede & Osborn, 2010; Nozaki et al., 2009). In other studies of adults with diabetes, depression has been shown to have an indirect effect on A1c through self-management behavior. A decrease in social support was associated with depression, which negatively affected the adoption of effective self-management behaviors (physical activity, dietary behavior, and self-monitoring blood glucose) (Egede & Osborn, 2010). Another study demonstrated that self-management mediated the relationship between depression and poor glycemic control (Helgeson et al., 2009). One study showed that self-management in adolescents with Type 1 diabetes, specifically measured by self-monitoring blood glucose levels, mediated the relationship between depression and poor glycemic control (McGrady, Laffel, Drotar, Repaske, & Hood, 2009). Compared with usual care, an intervention involving nurses who provided guideline-based, patient-centered management of depression and chronic disease (type 2 diabetes), significantly improved control of both the medical disease and the depression (Katon et al., 2010).

Diabetes-related distress. Despite the higher prevalence of clinical depression among patients with diabetes, there is another important factor within affect called diabetes-specific distress. Diabetes distress is related to, but distinct from, depression, with recent studies suggesting that the majority of the depression prevalence in patients with diabetes may in fact be distress about their diabetes and its self-management (Fisher, Skaff, & Mullan, 2007). Diabetes distress is defined as a patient's concerns about disease management, support, emotional burden, and

access to care (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008). Diabetes distress has been positively associated with negative life events and chronic stress due to disease (Fisher et al., 2007; Fisher et al., 2008). Diabetes-specific distress or anxiety has been more strongly associated with poor self-management and poor glycemic control than depression (Fisher et al., 2007; Herzer & Hood, 2010; Polonsky et al., 1995; Welch, Jacobson, & Polonsky, 1997). Diabetes-related distress was shown to indirectly influence glycemic control and to be mediated by self-efficacy (Nakahara et al., 2006; Nozaki et al., 2009). In a 20-year longitudinal follow-up study, there was a nonlinear relationship between psychological distress and mortality risk for men, such that moderate amounts of distress were protective, whereas high levels of distress substantially increased risk of mortality (Ferraro & Nuridden, 2006).

A clear research distinction has emerged between depression and distress, clarifying these important constructs in adults with type 2 diabetes. A third component of affect, attitude, is now introduced because of its known associations with self-efficacy and self-management.

Attitude. Positive and negative attitudes have been associated with self-reported self-management behavior performance (Anderson et al., 1993). The Diabetes Care Profile (DCP) is a comprehensive instrument designed to measure social and psychological factors important to a patient's adjustment to diabetes (Glasgow & Osteen, 1992; Peyrot & Rubin, 1997). As levels of depression increased, patients reported a more negative attitude. Correspondingly, as patients

reported lower depression scores, their positive attitude increased (Fitzgerald et al., 1996; Michigan Diabetes Research & Training Center, 2008). Two of the 14 scales embedded in the DCP instrument to measure the construct of positive and negative attitudes were significantly correlated with self-management and glycemic control (Fitzgerald et al., 1996). This further supports the connection between attitude, depression, and self-management.

Knowledge. Chronic disease self-management in patients with diabetes requires complex daily decisions about health care (Lippa et al., 2008). Diabetes self-management has been approached using simple rules and procedures, but effective self-management requires many of the same cognitive processes used in other complex domains (Klein, 2008; Lippa et al., 2008). Knowledge of the disease and healthy behaviors are in the cognitive domains most often studied in patients with diabetes or other chronic diseases. The social psychology definition of cognition is to “conceptualize, or to know” and refers to the ability to process information and apply knowledge. Knowledge is the understanding of diabetes as a disease, knowing the general principles of its treatment, and identifying skills needed for self-management (Beeney, Steward, & Welch, 2003). A debate continues about the role of knowledge in improving health behaviors in chronic disease management (Lippa et al., 2008).

Knowledge assessment, patient education, and coaching are examples of knowledge interventions studied in chronic disease management of patients with diabetes (Critchley et al., 2012). Educating patients with chronic disease to self-

manage their disease is, at least in the short run, effective in increasing functioning, reducing pain, and reducing health-care costs (Lorig et al., 1999; Sperl-Hillen et al., 2007). Diabetes-care knowledge has also been significantly associated with self-management (Abourizk et al., 1994; Beeney et al., 2003; Peyrot, 1985).

Duration of disease has shown to be a significant predictor of knowledge (Gazmararian et al., 2003).

Diabetes Self-Management Education (DSME). DMSE is also known as Diabetes Self-Management Training (DSMT) and is defined as a collaborative process through which people with, or at risk for, diabetes gain the knowledge and skills needed to modify behavior and successfully self-manage the disease and related conditions (Martin, Daly, & McWhorter, 2008). The American Diabetes Association has recommended diabetes self-management training as an integral component of a diabetes care plan (ADA, 2010). A Department of Health and Human Services Healthy People objective stated in 2010 was to increase the proportion of people receiving formal diabetes education from the 1998 baseline of 45% to 60% (Healthy People, 2010). The Centers for Medicare and Medicaid (CMS) reimburse for DSMT, if provided by accredited individuals or entities, for newly diagnosed patients with diabetes for an initial comprehensive diabetes education training that may not exceed 10 hours. Training after the initial diagnosis may not exceed two hours per CMS beneficiary in either an individual or group setting (Funnel, 2006).

Research has shown that as people become more motivated, they feel more competent to attain relevant outcomes (Williams et al., 2009). The concept of perceived competence versus perceived incompetence is central to the self-determination health behavior theory (SDT). SDT predicts that people with perceived competence, or knowledge, for managing their diabetes with respect to critical self-management behaviors were most effective in managing their diabetes (Williams et al., 2004). In studies intended to increase patients' knowledge, knowledge was not significant as a mediating mechanism to predict self-management (Lorig, Sobel, Bandura, & Holman, 1993; Lori, Seleznick et al., 1989). Recent literature established that knowledge, measured by patients having attended a diabetes education class, was the most significant predictor of successful diabetes self-management (Critchley et al., 2012; Holly, 2012). The study, entitled "Pathway Analysis of Lifestyle Change," showed that the educational aspect of the intervention program uniquely increased physical activity levels because it increased diabetes knowledge, improved mood, and increased self-efficacy (Critchley et al., 2012). Chronic disease knowledge is also related to demographic measures such as age, gender, education, and race (Gazmararian et al., 2003).

Health literacy. The level of a patient's health literacy has been shown in the literature to be a significant explanatory factor in understanding disease management. According to the Institute of Medicine (2004), health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health

decisions” (Ad Hoc Committee on Health Literacy, 1999). Health literacy is a multifaceted and complex construct that currently has several conceptualizations (Baker, Parker, & Williams, 1996). Health literacy consists of skills and abilities that enable the individual to navigate the health system, and is contingent on prior knowledge of vocabulary and conceptual knowledge of health and health care in particular (Baker et al., 1996). The skills included are reading fluency, prose literacy (the ability to read and understand text), document literacy (the ability to locate and use information in documents), quantitative literacy (the ability to apply arithmetic operations and use numerical information in printed material) and is strongly contingent on prior knowledge of vocabulary (familiarity with individual meanings of words). Health literacy was a significant predictor of an individual’s health status, even more than educational level, income, employment, or ethnicity (Institute of Medicine Committee on Health Literacy, 2004; Healthy People, 2010; IOM Report on Health Literacy, 1999 & 2004; Michielutte et al., 1996).

Patients with limited health literacy, compared to patients with adequate health literacy, have shown difficulty in understanding their clinical condition and its self-management (Gazmararian, Williams, Peel, & Baker, 2003). Health literacy has shown an indirect effect on diabetes self-care and glycemic control through its association with knowledge (Nath, Sylvester, Yasek, & Gunel, 2001; Osborn et al., 2010). Lower health literacy has been associated with poor glycemic control and higher health literacy was a significant predictor of good glycemic control, with an

odds ratio of 3.97 in a sample of persons with type 2 diabetes (Osborn et al., 2011; Schillinger et al., 2003).

Patients with chronic disease and lower literacy, even those who have been exposed to diabetes education, had poorer knowledge about their care and self-management behaviors (DeWalt, Berkman, Sheridan, Lohr, & Pignone, 2004). It is difficult to determine the exact relationship between health literacy and knowledge of disease as mean knowledge scores directly correlated with health literacy level for diabetes patients. More information on this association will assist in developing more effective interventions and educational programs (Gazmararian et al., 2003). Patients with limited health literacy may need more knowledge and social support to improve diabetes self-care management and outcomes (Osborn et al., 2011). Theorizing on the causal pathways between health literacy and predicting health status showed self-efficacy as a significant mediator (Donovan-Kicken, Macketer, Guinn, Tollison, & Breckinridge, 2012; Paasche-Orlow & Wolf, 2007).

Social support. It is widely recognized that social relationships and affiliations have powerful effects on physical and mental health (Berkman, 2000; Dunbar, Clark, Quinn, Gary, & Kaslow, 2008). Social support is a concept researchers have used to understand the impact of interpersonal relationships in chronic disease management (Kronish & Mann, 2010). The exact means by which social support contributes to health and the factors that mediate this relationship are not completely understood (DiMatteo, 2004). Two different dimensions have been utilized to describe perceived functional social support in the research: 1) emotional

and practical support domains (Berkman, Leo-Summer, & Horwitz, 1992), and 2) structural and functional social support (Uchino, Cacioppo, & Kiecolt-Glaser, 1996).

Patient self-management has shown significance in mediating the link between social support and health outcomes (Dunbar-Jacob & Schlenk, 2001). Further research indicates that social support with family and friends has a modest but significant role in diabetes self-management behavior (DiMatteo, 2004; Gallant, 2003; Glasgow et al., 1989). Social support showed the highest correlation with self-management behaviors, as it was 1.74 times higher in patients from cohesive families and 1.53 times lower in patients from families with conflict. The odds of achieving self-management are 2.35 times higher among patients with greater levels of social support (DiMatteo, 2004; Glasgow et al., 1989). A recent study of patients with diabetes showed health literacy having an indirect effect on diabetes self-management and glycemic control through its direct effect on and association with social support (Bains & Egede, 2010; Osborn et al., 2010).

There is considerable evidence that self-efficacy is one of the psychosocial pathways through which social support operates. For example, in studies of exercise, smoking cessation, and depression, the association between social networks and self-management behavior was significantly mediated by self-efficacy (Gulliver, Rohsenow, & Colby, 1995; McFarlane et al., 1995; Cutrona & Troutman, 1986; Duncan & McAuley, 1993). A review of social support literature suggests that the pathway from social support to health outcomes is likely mediated by

patient self-management (DiMatteo, 2004; Druley & Townsend, 1998; Hagedoorn et al., 2000; Martin et al., 1996). The following sections share more detailed research regarding the two dimensions of social support: 1) emotional and practical support and 2) structural and functional social support domains.

Emotional support, as a social support construct, has been described as “having empathy for and providing encouragement for the self-management behaviors needed in diabetes self-care.” Practical support has been described as “the willingness to provide assistance with helping pick up medications or transportation to physician visits” (Berkman et al., 1992).

A second way this construct has been described is as a structural/functional dimension identified by the effects of social support on self-management behavior as functional (e.g., family cohesion, emotional support) and structural (e.g., marital status, living arrangement) social support (DiMatteo, 2004; Uchino et al., 1996). These factors are designated to impact health through health behavior (self-management), psychological (self-efficacy), and physiological pathways (Berkman, 2000). Significant linkages between the characteristics of the family setting in which disease management takes place and self-management behavior have been found (Brubaker & Roberto, 1993; Fisher et al., 2000; Hank & Bruber, 2009). In one study, the family context was defined to include family support, functioning, efficacy, family structure, and knowledge and skills (Dunbar et al., 2008). Family support by ethnicity may vary but has shown significance in promoting self-management behaviors in Native American, African American, and European

American adults with type 2 diabetes (Brody et al., 2008; Eapple, Wright, Joish, & Bauer, 2003; Trief et al., 2001; Williams & Bond, 2002). In one meta-analysis of social support studies for adults living with others, the odds of improved self-management were 1.38 times higher than among those living alone (DiMatteo, 2004; Rosenthal and Rosnow, 1991).

Chronic disease literature on depressive systems cites that direct favorable effects were found by having a partner, having many close relationships, greater feelings of mastery, greater self-efficacy expectations, and high self-esteem. Receiving instrumental support and needing more support assistance for tasks was associated with more depressive symptoms, especially in diabetes patients (Penniz et al., 1998).

Social support is not uniformly, nor always, beneficial (Thomas, 2009). Negative support from family and friends, and family conflict, are related to poorer, psychologically problematic interactions with medical teams (DiMatteo, 2004; Norton et al., 2005). Understanding the partnership between patients and their social network, which includes their health-care provider(s), is considered an important psychosocial factor in the care of patient diagnosed with diabetes (DiMatteo, 2004).

In the review of chronic disease management and health behavioral theory, varying impacts of social support have been found. Social networks were not validated as significant by provider and patient focus groups used in developing the patient activation measure (PAM) within the biomedical chronic disease system

(Hibbard et al., 2004). In an important Self Determination Theory (SDT) model study, perceived autonomy support (social support) did not show a direct significant association with change in A1c levels. However, perceived autonomy support did appear to have an indirect effect associated with predicting changes in perceived competency (self-efficacy) and self-management—both factors which showed significance in predicting maintenance of A1c changes (Williams et al., 2005).

Self-efficacy. As previously noted in the biopsychosocial framework, chronic disease management models, and health behavior theoretical models, self-efficacy has been determined to be one of the most, if not the most, important psychosocial factor. In this research, due to the perceived significant role of self-efficacy as shown in health behavior theoretical research on self-management achievement, it was posited to be the mediator between the key psychosocial factors under study and self-management. A summary review of the literature and related health behavior theories regarding the concept of perceived self-efficacy as it relates to psychosocial factors and self-management behaviors follows.

Diverse lines of research support the role of perceived self-efficacy in different spheres of functioning (Bradley, 1994; Peryot, 1994). A number of meta-analyses of findings in different domains of functioning confirm the influential role of perceived self-efficacy in human adaptation and change (Holden, 1991; Holden, Moncher, Schinke, & Barker, 1990; Multon, Brown, & Lent, 1991; Stajkovic & Luthans, 1998). The beliefs people hold about their perceived self-efficacy (their ability to exercise control over events that affect their lives) influence the choices

they make, their aspirations, level of effort and perseverance, resilience to adversity, vulnerability to stress and depression, and performance or accomplishments (Bandura, 1998).

Social cognition theorizes that a person's confidence in his or her ability to perform health behaviors influences the extent to which the person will follow through with them. In studies where multiple psychosocial constructs are examined, perceived self-efficacy consistently emerges as a distinct and powerful predictor of short and long-term self-management behavior success while controlling for other possible determinants (Gonder-Frederick, 2002; McCaul, Glasgow, & Shafer, 1987; Mirowsky & Ross, 2010). Perceived self-efficacy, defined as the degree of confidence persons have in their perceived ability to perform specific behaviors or capably respond to a situation, has been associated with self-management, health, and functional outcomes, including glycemic control (Bandura, 1977, 1997; Berkman, 2000; Grembowski et al., 1993; McAuley, Jerome, Evasky, Marquez, & Ramsey, 1993; Mendes de Leon, Seeman, Baker, Richardson, & Tinetti, 1996; Seeman, Rodin, & Albert, 1993; Tinetti & Powell, 1993).

Support for the importance of perceived self-efficacy in diabetes self-care management comes from several studies showing that higher self-efficacy is directly associated with higher self-rated self-management behavior (McCaul et al., 1987; Padgett, 1991; Williams et al., 2005; Senecal et al., 2000). In cross-sectional studies of patients with type 2 diabetes, self-efficacy and diabetes coping (affect) were associated with improved self-management behaviors (adherence) and better

glycemic control (Ikeda et al., 2003; Mooy et al., 2000). Self-efficacy as a major basis of action has been found to directly reinforce self-management, and self-management has been found to directly relate (positively) to good future glycemic control (A1c) (Bandura, 1998; Nakahara et al., 2006; Nelson, McFarland, & Reibner, 2007; Nozaki et al., 2009; Sacco et al., 2005, 2007). Self-efficacy has received increasing recognition as a predictor of health behaviors, including self-management. In comparing predictors of performance of self-management regimens in patients with diabetes, neither knowledge nor social support predicted self-management behavior. Perceived self-efficacy was the only factor that predicted performance of each measured aspect of self-management: diet, glucose monitoring, and self-administration of insulin (McAuley, 1992; 1997).

Two observational studies showed no association between high self-efficacy and health literacy; however, in type 2 diabetes management intervention trials, subjects with low health literacy were shown to have more improvement than subjects with adequate literacy, which suggests a possible moderating role of self-efficacy (Paashle-Orlow & Wolf, 2007).

Self-efficacy, as confidence in patient-physician interactions, has been positively associated with improved self-management (Brownlee-Duffeck et al., 1987; McCaul et al., 1987; Peyrot, 1990; Robiner & Keel, 1997) and greater clinical outcomes (Kaplan, Greenfield, & Ware, 1989). Self-efficacy is situation and task-specific (Bijl, Poelgeest-Eeltink, & Shortridge-Baggett, 1999). Individuals can feel efficacious in one situation, but less efficacious in a different situation. Individuals

with diabetes, for example, perform specific self-management tasks such as eating an appropriate diet, getting proper exercise, checking blood glucose levels, taking oral medications and/or insulin, and often, balancing the amount of medication or insulin respective to the amount of food intake, amount of exercise, and varying blood glucose levels on a daily basis (Wallston, Rothman, & Cherrington, 2007). Behaviors required for diabetes management differ significantly from behaviors needed to manage other disabilities and chronic conditions.

Research has suggested that people with diabetes know that they should exercise, but many still fail to do so (CDC, 2011). For example, knowledge is a precondition for behavioral change, but on its own, it is insufficient (Bandura, 1998). A more important influence within Social Cognitive Theory (SCT) is self-efficacy, because it influences the activities in which people choose to engage, the energy they put into these activities, and the persistence they demonstrate in the face of obstacles (Bandura, 1997; 2004).

Studies comparing a static and a dynamic measure of self-efficacy as a mediator in a causal model between personality traits (dispositional optimism and pessimism) and health outcomes revealed that positive changes in self-efficacy predicted positive changes in health outcomes. Personality traits were unrelated to the health outcomes, either directly or indirectly, through changes in self-efficacy (Hankonen, Vollmann, Renner, & Absetz, 2010).

The discussion in the literature of the influence of self-efficacy at varying times during the health behavior change process implies it is consistent, whether at

the initial adoption or the maintenance phase (Bandura, 1997; Renner, Hankonen, Ghisletta, & Absetz, 2012; Rothman, 2000). Psychosocial emotional factors, such as social support, depression, distress, and self-efficacy, can negatively affect the adoption and maintenance of health behaviors (McAuley, 1992, 1993; Renner et al., 2012). Self-efficacy was shown to be a significant predictor of physical activity in the adoption phase (during intervention at three months) and the maintenance phase (four months post intervention) (McAuley et al., 2003). In a longitudinal intervention study, self-efficacy was a significant mediator of physical activity, eating habits, and weight loss across different measurement points in time (Blanchard et al., 2007; Roach et al., 2003; Warziski, Sereika, Styn, Music, & Burke, 2008). One recent study has not shown self-efficacy to be a significant mediator (Annesi, 2011). With few exceptions, self-efficacy consistently has been shown to be a mediating variable influencing individual self-management behavior and resulting outcomes.

Self-management Behaviors Self-management behavior has been studied at the macro (system) level as medical chronic disease management and at the micro (individual) level as self-management behavior. While both aspects are discussed in more detail below, the micro view of self-management behavior (SMB) is the focus for this research.

The nature of diabetes requires intensive self-management behaviors (SMB). A clearer understanding of the mechanisms through which psychosocial factors support patients' achievement of self-management behaviors is needed

(Grey et al., 2001). Patients with type 2 diabetes need to interpret their symptoms and make self-management decisions daily and over the long term (Paasche-Orlow & Wolf, 2007). Self-management behavior is now the accepted term used to describe the day-to-day decisions and activities in which patients engage, with the help of people around them, in order to live with and control their illnesses (Bodenheimer, Wagner, & Grumbach, 2002; Lorig et al., 1999). The term *self-management* is preferred and has been chosen over *adherence*, *compliance*, or *activation* (medical chronic disease terms) to reflect the role of agency and self-determination in health-promoting, chronic disease self-management behaviors (Bandura, 1997; Williams et al., 1998). Prior research demonstrates that interventions providing diabetes self-management education may improve glycemic control (Brown, 1999).

Evidence suggests that certain systematic approaches in which patients with proper psychosocial support and an understanding of behavioral theory take the lead in managing their chronic condition can improve their health, advance or sustain their quality of life, and reduce incapacity (UK Department of Health, 2010). However, few patients receive the support they need to attain self-management (Sperl-Hillen & Beaton, 2007). The greatest challenge to contemporary diabetes treatment is achieving patient ownership and effective self-management of the disease (Inzucchi et al., 2012; Suls & Rothman, 2004). Psychosocial variables generally predict levels of self-management over demographic variables (Glasgow

et al., 1989). A focus on these variables may well serve research into improving diabetes outcomes.

Self-management behavior (SMB) is defined as any action that a patient engages in that is seen as health-promoting and that could be recommended by a health-care clinician (Sackett & Haynes, 1979; Lorig et al., 2002). Specific to patients diagnosed with type 2 diabetes, important self-management behavior is defined as achievement of specific, evidence-based self-care behaviors, including eating a healthful diet, increasing physical activity, self-monitoring blood glucose testing (SMBG), reducing alcohol and tobacco use, and taking needed medications (Bodenheimer et al., 2002; Funnell, 2006; Resnick, Bardsley, & Ratner, 2007; Saydah, 2004).

In order to manage diabetes, an adult with diabetes needs to perform multiple different self-management activities. The performance of self-management activities for diabetes have been shown to improve glycemic control and decrease complications associated with the disease (Heisler, Piette, Spencer, Keiffer, & Vijan, 2005; Lee et al., 2009; Whittemore, Melkus, & Grey, 2005). If adults participate in their self-management behaviors, symptoms can be alleviated and physical and mental health outcomes improved (Harvey et al., 2008). If an adult with type 2 diabetes does not make self-management behavior changes, factors such as obesity and physical inactivity may increase the risk of morbidity and mortality, decrease quality of life, and increase health care complications (costs).

Between 1996 and 2001, a federally funded landmark clinical trial titled the Diabetes Prevention Program (DPP) proved that a diverse group of adults could successfully undertake intensive life interventions (diet and exercise self-management) to delay the onset of diabetes or prevent it altogether (Diabetes Prevention Program Research Group, 2003). The DPP demonstrated that compared with those with no intervention, the study participants with intensive lifestyle intervention had reduced incidence of type 2 diabetes, by 58%, and those with the medication intervention had reduced incidence of type 2 diabetes by 31% over 2.8 years (Knowler et al., 2002).

Self-management behaviors (diet, exercise, and SMBG) have been shown to mediate the relationship between change in perceived competence (knowledge) and change in glycemic control (A1c) (Williams et al., 2005).

Self-efficacy, as a mediator variable, has been shown to directly influence self-management behaviors in several studies. Positive self-efficacy was associated with positive self-management behaviors in patients with diabetes (Crabtree, 1986; Hurley & Shea, 1992; McCaul et al., 1987; Nelson et al., 2007; Padgett, 1991). Self-management behaviors success was determined to stem more from the patient's belief in their efficacy, or confidence that they could achieve needed changes (Taal, Rasker, Seydel, & Wiegman, 1993). Factors which influence how one behaves or performs an activity—such as perceived self-efficacy, outcome expectancies, and depression and anxiety—play an essential role in the performance of self-management behaviors by adults with a chronic condition (Tucker et al.,

2011). Motivators for health behaviors include increased self-efficacy (Roach et al., 2003). Each of these psychosocial factors have shown correlation with the actual performance of self-management behaviors for a disease (Bai, Chiou, & Chang, 2009; Williams & Bond, 2002).

There is significant agreement on type 2 diabetes clinical evidence-based guidelines, including glycemic control, the importance of dietary self-care, physical activity, self-monitoring of blood glucose levels (SMBG), tobacco smoking, and aspirin use (Brink, 2009; CDC, 2011; NICE, 2008). Individual intervention programs have been associated with changes in psychosocial factors such as affect, knowledge, and social support (Critchley et al., 2012). Little research has focused on understanding the actual impact of multiple psychosocial factors process on self-management behavior change and why certain intervention programs seem to be more effective than other programs (Critchley et al., 2012). Understanding more about how the pathways between psychosocial factors influences the uptake of behavior or self-management is necessary.

This research examined the direction and pathways between several primary psychosocial factors, including self-efficacy, and self-management behaviors. The following sections will discuss each of the study self-management behaviors and their known association with psychosocial factors, self-efficacy, and outcomes. The self-management behaviors included in this research are A1C, dietary self-care, physical activity, self-care ability, self-monitored blood glucose, tobacco use, and aspirin use.

Dietary self-care. Although many individuals with diabetes fail to follow the recommended dietary self-care activities on a regular basis, it is generally agreed that dietary self-care (along with exercise) is one of the two most central elements of diabetes self-management (Ary, Toobert, Wilson, & Glasgow, 1986; Brink, 2009; CDC, 2011). The majority of individuals with type 2 diabetes are overweight or obese (approximately 80%) (Sluik, Boeing, & Montonen, 2011). In 2000, 20% of the US population was reported in the obese category of BMI >30, compared to 26% reporting obese BMI in 2008. During this same time period, the overweight category remained level from 2000–2008 at 36.5 % (CDC, 2010). Despite intense efforts over the past decade to encourage healthy diet and regular physical activity, there are mixed results; rates of obesity have remained high and diabetes is more prevalent (National Center for Health Statistics, 2010). The percentage of adults who consume the recommended servings of vegetables per day has remained low (CDC, 2010). Even a modest reduction in weight (5–10%) achieved by dietary means improves glycemic control and reduces other clinical risk factors (Inzucchi et al., 2012).

In studying the level of health-related self-efficacy at baseline, there was no effect on waist circumference change directly; rather, the amount of change in self-efficacy by a diabetes intervention study appears to be critical understanding or knowledge (Hankonen et al., 2010). Eating behavior was not found to mediate psychological variables in research conducted and supports the order of the

proposed conceptual model where self-efficacy is depicted as mediating knowledge (Critchley et al., 2012).

Physical activity. Physical activity plays an important role in self-management in patients with type 2 diabetes. It affects metabolic functions and impacts glucose levels, which are critical to a person with diabetes. The prevalence of overweight and obesity in adults had risen to 65% in 1999–2000; these factors confer significant risk for developing cardiovascular disease, diabetes, and cancer (Eyre, Robertson, & Klein, 2004). Physical inactivity is a key risk factor for type 2 diabetes. Even modest levels of physical activity have been associated with a lower risk of incident diabetes, compared with lower levels of activity (Fretts et al., 2012).

In conducting a systematic analysis of qualitative research of patients with heart failure, social cognitive theory proved to be a useful framework for developing interventions to support patients in undertaking and maintaining physical exercise programs. Those with lower self-efficacy were shown to have set lower goals, have lower expectations for outcomes, and be less willing to push through when experiencing obstacles (Tierney et al., 2011). Those who have a higher scored perceived self-efficacy are also better at managing their health behaviors, such as physical activity (Bandura, 1997). When developing an exercise program for obesity, self-efficacy and mood were found to improve treatment effects (Baker et al., 2011; Critchley et al., 2012).

Research studies on a variety of barriers and motivators that influence behavior change processes such as physical activity have been conducted with

adults with type 2 diabetes. Barriers to engaging in physical exercise include perceived anxiety (affect) and a lack of social support (social support) (Ng & Jeffery, 2003; Wilcox, Castro, King, Housemann, & Brownson, 2000). In a longitudinal intervention study, perceived self-efficacy was a significant mediator of physical activity across different points in time (Blanchard et al., 2007; Roach et al., 2003; Warziski et al., 2008).

Self-monitored blood glucose testing. Self-monitoring of blood glucose (SMBG) is widely recognized as a core component of effective diabetic self-management (ADA, 2010; Polonsky et al., 2011; Brody et al., 2008; Rodbard et al., 2007). SMBG is a primary feedback system through which patients with type 2 diabetes can assess the effectiveness or need for change in their medical care and self-management. To manage hyperglycemia or hypoglycemia, self-monitoring blood glucose levels (SMBG) is often recommended, along with exercising and eating properly. Hyperglycemia in diabetes was noted consistently as one of the factors associated with these poorer outcomes in adults with diabetes (ADA, 2012; Psarakis, 2006). Most evidence indicates that more frequent SMBG contributes to good glycemic control among patients with type 1 and type 2 diabetes. Support for self-management appears to be indirectly associated with glycemic control through its promotion of SMBG (Brody et al., 2008).

Regular use of SMBG leads to reductions, not increases, in depressive symptoms and diabetes distress over time for the large number of moderately depressed or distressed type 2 patients in poor glycemic control. Changes in

affective status are independent of improvements in glycemic control and changes in SMBG frequency for these patients (Fisher et al., 2011). Social support was linked indirectly to glycemic control through the promotion of SMBG (Brody et al., 2008; Polonsky et al., 2011) Knowledge has been shown to be a strong predictor of SMBG testing (Glasgow et al., 1989). A 12-month randomized clinical trial demonstrated that appropriate use of structured SMBG testing significantly improved glycemic control (reduction in mean A1c levels in the structured SMBG testing group was about 20% over the usual care group) and facilitated more timely/aggressive treatment changes in noninsulin-treated type 2 diabetes without decreasing general well-being (Polonsky et al., 2011).

Glycemic control (A1c). The primary clinical self-management measure in this research will be the changes in glycemic control (A1c) levels, which is the most commonly studied clinical outcome variable in patients with type 2 diabetes. In general, every percentage point drop in A1c blood test results (e.g., from 8.0% to 7.0%) can reduce the risk of microvascular complications (eye, kidney, and nerve diseases) by 40% (CDC, 2011). The absolute difference in risk may vary for certain subgroups of people.

Self-management behaviors had a direct association with future A1c levels (DeWalt, Boone, & Pignone, 2007; Nakahara et al., 2006). Other psychosocial factors, including social support, diabetes-related distress, daily burden and emotion-focused coping, the belief that type 2 diabetes is a serious problem, and depression, were significantly associated with higher A1c levels, indirectly through

self-efficacy (DeWalt et al., 2007; Nakahara et al., 2006). Being married, greater adherence with taking medications, and self-monitoring blood glucose testing were associated with lower A1c levels (Daly et al., 2009).

Recent studies using structural equation modeling or hierarchical stepwise multiple regression showed that psychosocial factors are more directly associated with self-management behaviors and indirectly related to A1c and other clinical outcomes (Williams et al., 2009, 2005; Nozaki et al., 2009; Brody et al., 2008; Nakahara et al., 2006). An examination of the causal relationship between psychosocial factors and glycemic control in a group of diabetic patients at baseline, 6 months, and 12 months following baseline found that self-efficacy directly reinforced self-management, and self-management was associated with glycemic control (Nakahara et al., 2006). Low resilience and diabetes-related distress were associated with fewer self-management behaviors and showed a strong association with predicted A1c at one year (Yi et al., 2008).

Change in weight and/or waist circumference has also been a measure representing healthy changes in diet and exercise, with direct association to A1c levels (Annessi, 2011). With regard to glycemic control, no direct relationship between literacy and A1c has been demonstrated (DeWalt et al., 2007).

Dispositional factors such as trust, personality, and knowledge were not related to A1c (DeWalt et al., 2007).

In type 2 diabetes, maintaining glycemic levels close to the nondiabetic range is strongly associated with reduced microvascular complications (Nathan et

al., 2009). In general, every percentage point drop in A1c blood test results (e.g., from 8.0% to 7.0%) can reduce the risk of microvascular complications (eye, kidney, and nerve diseases) by 40% (The Diabetes Control and Complications Trial Research Group, 1993). Effectively managing hyperglycemia has been a top priority for type 2 diabetes, but more recently, due to studies of aggressive glycemic control, the importance of managing hypoglycemia has also been recognized.

Exogenous Characteristics

Evidence shows demographic, socioeconomic, and clinical factors influence diabetes self-management in adults, including age, gender, duration or length of time since being diagnosed with diabetes, smoking, alcohol use, systolic blood pressure, and number of and type of medications (Cederholm et al., 2008; Haussler, 2005; Gudbjornsdottir, 2003). Age, income, and employment status have emerged in important relationships with diabetes self-management and outcomes (NCHS, 1965). For the adult with type 2 diabetes, individual or socio-demographic factors have been shown to have either a positive or negative influence on the performance of self-management activities (Chiu et al., 2010). Age, sex, level of education, marital status, race/ethnicity, and socioeconomic status have all been noted to influence the performance of self-management behaviors for chronic disorders (Chiu et al., 2010; Jenerette & Phillips, 2006; Jerant et al., 2005; McDonald-Miszczak & Wister, 2005; Nagelkerk et al., 2006). A recent study of adult patients with type 2 diabetes found factors such as insurance, demographics, and health risk indicators were not significantly predictive of self-management (Holly, 2012).

Based on the known positive or negative impact each of these factors can have on the performance of self-management behaviors, it is essential that they be included in the model when developing an understanding of the influence of psychosocial factors on self-efficacy and self-management on outcomes.

Demographic factors. For the purposes of this study, individual demographic characteristics comprise the controlling variables of age, gender, and race/ethnicity. Each of these individual characteristics may play a role in the performance and/or the continued performance of self-efficacy, self-management behaviors, and outcomes in diabetes (Bayliss et al., 2003, 2007; Dunbar et al., 2008; MacInnes, 2008). The influence age and gender have on the actual performance of self-management activities is unclear. The effect of each of these may be dependent upon specific activity required (MacInnes, 2008). It is possible that these exogenous factors directly influence the psychosocial factors and indirectly influence self-efficacy and self-management behaviors.

Age. Based on a national health survey conducted in 1989, the median age of adults without diabetes is 40 years, and for adults with diabetes, the median age is significantly higher, 63 years (Cowie & Eberhardt, 1995). As an individual gets older, the risk of having type 2 diabetes increases (ADA, 2012). Based on data collected from the 2005–2008 National Health and Nutrition Examination Survey, the prevalence of undiagnosed diabetes increases greatly between age 40 and 49 years and reaches a peak in people aged 60–74 years (Eyre et al., 2004). The

prevalence of individuals ages 20–44 is 3.7%, 13.7% for ages 45–64, and 26.9% for ages greater than or equal to 65 (CDC, 2011).

The influence of an individual's age varies based on the self-management behavior being studied (ADA, 2012). The performance of self-management behaviors tends to increase as an individual ages (Grey et al., 2006; MacInnes, 2008). In a cross-sectional study, age was a significant predictor of dietary self-management, with older adults reporting higher levels of dietary self-management (Vijan et al., 2005; Wen, Shepherd, & Parchman, 2004). Individuals who are considered elderly or frail may perform self-management behaviors less and be more dependent upon spouses or caregivers to provide or assist with recommended self-management behaviors (Brewer-Lowry, Arcury, Bell, & Quandt, 2010; Grey et al., 2006). Younger adults with diabetes report more barriers and less self-management than older adults (Ashby et al., 2006; Glasgow, Hampson, Strycker, & Ruggiero, 1997; Vijan et al., 2005; Wen et al., 2004).

Younger age was independently associated with higher diabetes-related stress, increased chronic stress, higher depressed affect, negative life events, and eating healthier foods and exercising less frequently, lower diabetes self-efficacy and higher A1c levels. Interactions found that younger patients with high stress and/or low self-efficacy were more likely to have higher A1c levels than older patients (Hessler, Fisher, Mullan, Glasgow, & Masharani, 2011).

Gender. Type 2 diabetes showed a pronounced female excess in the first half of the last century, but is now equally prevalent among men and women in

most populations, with some evidence of male preponderance in early middle age. Men seem more susceptible than women to the consequences of obesity, possibly due to differences in insulin sensitivity and regional fat deposition. Women are, however, more likely to transmit type 2 diabetes to their offspring (Gale & Gillespie, 2001).

Gender has also shown significance in relation to self-management of type 2 diabetes. Women are more likely to follow self-management regarding medication regimens, where men are more likely to follow prescribed physical activity regimens (Burnette et al., 2004; MacInnes, 2008). Women are more likely to ensure that a spouse or partner is performing recommended self-care activities versus performing self-management themselves (Grey et al., 2006).

Race/ethnicity. After adjusting for population age differences, 2007–2009 national survey data for people aged 20 years or older indicate that 7.1% of non-Hispanic whites, 8.4% of Asian Americans, 11.8% of Hispanics, and 12.6% of non-Hispanic blacks had diagnosed diabetes. Among Hispanics, rates were 7.6% for both Cubans and for Central and South Americans, 13.3% for Mexican Americans, and 13.8% for Puerto Ricans. Compared to non-Hispanic white adults, the risk of diagnosed diabetes was 18% higher among Asian Americans, 66% higher among Hispanics, and 77% higher among non-Hispanic blacks. Among Hispanics compared to non-Hispanic white adults, the risk of diagnosed diabetes was about the same for Cubans and for Central and South Americans, 87% higher for Mexican Americans, and 94% higher for Puerto Ricans.

Race/ethnicity status has influenced the performance of self-management behaviors for chronic disorders, including diabetes (Hawthorne et al., 2008; Millett et al., 2007; Smith, Walker, Fields, Brookins, & Seay, 1999). The nature or amount of self-management behaviors performed may also vary by other socioeconomic variables, such as educational status and income levels (Dunbar et al., 2008; Grey et al., 2006).

Individuals of minority status (African American, American Indian, Asian American, Pacific Islander, or Hispanic/Latino) having lower levels of education, belonging to a lower financial bracket, or living alone are more likely to experience barriers associated with the performance of self-management activities (Bayliss et al., 2007; Bayliss et al., 2003; Dunbar et al., 2008; Gallant et al., 2007; MacInnes, 2008; Nagelkerk et al., 2006; Tang, Brown, Funnell, & Anderson, 2008).

Racial/ethnic discrimination may pose barriers to self-management, as a recent study associated approximately a 50% lower marginal probability of receiving an A1c test, foot exam, and blood pressure exam (Ryan, Gilbert, Gee, & Griffith, 2008).

Socioeconomic factors. Socioeconomic factors, including educational level and income level, reveal an important relationship between health characteristics in patients with diabetes. In several studies, the prevalence of adults with type 2 diabetes has been inversely related to education, occupation, and income levels (Cowie & Eberhardt, 2001; Everson, Siobhan, Lynch, & Kaplan, 2002). Even factoring in age, persons with type 2 diabetes have less education and lower income

levels and are less likely to be employed than the general population (Cowie & Eberhardt, 2001).

Socioeconomic status has been shown to have an influence on the performance of self-management behaviors for chronic disorders, including diabetes (Hawthorne et al., 2008; Millett et al., 2007; Smith et al., 1999). This study included exogenous variates for the SES factors of education level, household income level, and employment status.

Educational level. Education is an important indicator of socioeconomic situation (Robbins, Vaccarino, Zhang, & Kasl, 2001). Based on the 1989 National Health Interview Survey (NHIS), the percentage of those with non-insulin-dependent diabetes (NIDDM) who had completed some college was 21%, compared to 40% among adults with non-diabetes and 51% among those with insulin-dependent diabetes (NIH, 1995).

In several studies, education level, measured as years in school, shows evidence of a positive correlation between the number of years in education and less glucose impairment. Healthy subjects had a significant increase in the mean number of years of education (9.2), compared to subjects who had impaired glucose regulation (8.8 years) (Hu et al., 2004). Another ten-year longitudinal study of adults with type 2 diabetes showed higher levels of education were associated with a greater risk of autoimmune diabetes (Olsson, Ahlbom, Grill, Midthjell, & Carlsson, 2000).

Income level. Income level based on relationship to the federal poverty levels has shown that families with lower incomes have a higher prevalence of diabetes compared to the total population, and the difference has become greater over time (Cowie & Eberhardt, 2001). Even controlling for age, non-insulin-dependent individuals with diabetes were less likely to be employed than adults without diabetes (Cowie & Eberhardt, 2001). A review of the National Health and Nutrition Examination Survey (NHANES III) conducted by the National Center for Health Statistics at 89 US survey locations between 1988 and 1994 reported that one-fifth of participants with type 2 diabetes had incomes below the federal poverty level (Nelson, Reiber, & Boyko, 2002).

Employment status. Employment status for people with diabetes has changed only slightly, but there is a suggestion of a sex-related change. In 1979–81, 47.3% of adults age 45–64 with diabetes reported being in the labor force (i.e., employed or seeking employment). This is nearly identical to the 47.0% of NIDDM reporting this in 1989. However, the percentage has decreased for diabetic men age 45–64, from 64.1% in 1979–81 to 57.1% in 1989, and has increased for women with diabetes during this period, from 32.0% to nearly 38.3% (Cowie & Eberhardt, 2001).

Marital status. For adults with type 2 diabetes, marital status and living with another person increases self-management behaviors modestly (DiMatteo, 2004). Family cohesion and marital adjustment are empirically related to self-management in adults with type 2 diabetes (DiMatteo, 2004; Trief, Himes, Orendorff, &

Weinstock, 2001; Trief, Wade, Britton, & Weinstock, 2002). The odds of effective self-management in adults are 1.27 times higher if married than if unmarried. A review of fifty-one studies of the correlation of self-management with marital status produced effect sizes ranging from -.25 to .44, with the mean being significant and robust (DiMatteo, 2004).

Clinical factors. Clinical characteristics such as length of time with the illness (duration), symptom burden, and other comorbidities can influence how well an individual performs self-management behaviors. Clinical characteristics have been noted to influence the performance of self-management behaviors either positively or negatively (Aljaseem et al., 2001; Janz et al., 2007; Kerr et al., 2007; Mann, Ponienman, Leventhal, & Halm, 2009; Molasiottis, Stricker, Eaby, Velders, & Coventry, 2008; Rao & Cohen, 2004).

The more symptoms an individual experiences, and the overlapping or competing effects of these symptoms with required self-management behaviors, can negatively impact their performance (Cleeland et al., 2000; Hofman et al., 2007; Kerr et al., 2007; Oberst et al., 1991; Reiner & Lacasse, 2006).

The greater the number of medications an individual takes, the more complex their treatment plan, and the severity of their illness can also have a negative impact on the performance of self-management behaviors (Bayliss et al., 2007; Mann et al., 2009; Piette & Kerr, 2006).

In summary, clinical characteristics associated with an individual's health or disease state negatively influence the performance of self-management behaviors,

with the exception of length of time the individual has had the condition. The amount of influence these variables have on the actual performance of self-management behaviors may be influenced by certain psychosocial or behavioral characteristics; these will be explored in the following section. Clinical intensity baseline factors included in this study are length of time with the illness (duration), baseline BMI (calculated using baseline weight and waist circumference), and use of insulin.

Duration - length of time with disease. The longer an individual has a chronic condition such as diabetes, the more likely they are to recognize symptoms and perform self-management behaviors (MacInnes, 2008).

Baseline BMI. Several studies have shown significant correlation between baseline and follow-up clinical values, including BMI, weight, and waist circumference. For example, in a similar study, A1c at baseline remained as a predictor of A1c at 6 months and 12 months after baseline (Nakahara et al., 2006). Baseline A1c has also been significantly associated with age, dietary care, and the total scores of PAID, SES, and self-efficacy scales, even after adjustment for demographic, clinical, and other psychosocial factors (Nozaki et al., 2009).

Insulin use. In studying adults with type 2 diabetes, the number and type of medications a person is taking has been correlated with decreased rating of health-related quality of life (Stewart, Woodward, & Cutler, 2005; Wexler et al., 2006). Individuals who take a large number of medications rate their own health as poorer than those who take fewer (Stewart et al., 2005). It was theorized that sicker

patients might be prescribed insulin, and an increased burden due to the insulin regimen itself contributed to a decrease in self-management and health-related quality of life (Wexler et al., 2006). The use of insulin and the number of medications taken has also been correlated, although not completely collinearly, with the severity of disease progression and comorbidities, as well as with lower quality of life (Wexler et al., 2006).

Summary of Relevant Literature (2006-2013)

An extensive amount of literature is available related to type 2 diabetes. Reviewing the research from the psychological, medical (biological), and biobehavioral disciplines unveiled theoretical and operational models used in the care of patients with type 2 diabetes. Most prevalent among the literature were: 1) the biopsychosocial theoretical framework from the health psychology discipline (Engel, 1997; Schwartz & Weiss, 1978; Suls & Rothman, 2004); 2) several health behavior theories from the behavioral discipline (Araújo-Soares et al., 2010; Bandura, 1977; Darker et al., 2010; Hagger, 2009, 2010); and 3) the patient activation model (PAM) from the medical (biomedical) chronic disease management models (Hibbard et al. 2004; Rosen et al., 2006).

From this review, a better understanding of the influence of psychosocial factors on self-management in adult patients with type 2 diabetes was established. Specifically, common to all the models is the significant role self-efficacy and perceived self-efficacy play in patient self-management, leading this researcher to

study it as a mediating factor, distinguishing the theoretical model of this study from previous work.

The following table (Table 2) outlines a summary of relevant literature of adults with type 2 diabetes. Current literature (from 2006–2012), along with a few important foundational articles between 1991–2006 with significance concerning health behavior theories, psychosocial factors, self-efficacy, self-management, and clinical and HRQOL outcomes, were included.

Table 2

Significant Studies of Diabetes and Other Health Behaviors Related to Self-efficacy and Self-management and Clinical and QOL Outcomes—2006 to Present

No	Publication Date, Author	Location, Study Year, Sample (N)	Study Intent and Method	Study Factors & Findings	Study Method	Effect Direction & Size
1	(2006) Nakahara et al.; Prospective Study	Japan; T2DM; outpatient clinic; 256 patients	Causal relationship between psychosocial factors and A1c (6 mo. and 12 mos.)	SE (Baseline) directly influenced SBM and SBM directly associated with A1c (6 mo.) All other PS factors were mediated by SE to A1c	SEM – 2 models (6 mos. and 12 mos.) GFI/AGFI indices	Social Support, diabetes distress; daily burden; emotion-focused coping (indirect through SE) SE direct to Self-Mgmt. (SMB). (SMB) direct to A1c
2	(2009); Nozaki et al.; Cross-sectional and prospective study;	Japan, Outpatient Clinic Adults with type 2 diabetes; 304 patients	Psychosocial Variables & A1c at Baseline and 12 months	Outcome Predictors of A1c = Trmt. Satisfaction; PAID, Age and Diet Trmt. regimen (diet only or medication)	Self-report Inventories and Medical Record Findings; Hierarchical Stepwise Multiple Regression	Baseline A1c & diet/meds. Regimen significantly associated with A1C at 12 months ($R^2=47\%$); Diabetes Trmt. Satisfaction & PAID (emotional distress) significantly associated with future A1c ($R^2=12\%$); A1c $\uparrow .17\%$
3	2010, Osborn et al.; Factor Identification	US; Outpatient Clinic; T2DM; 160 adult patients	Mechanism by which health literacy is linked to SMB and A1c and Psychosocial factors (Social, Knowledge, Attitude)	Health Literacy has indirect effect on SMB & A1c and direct association with social support.	CFA, SEM, used RMSEA and CFI indices, 2 Models were compared	\uparrow Knowledge \downarrow Fatalism, & \uparrow Social Support were independent, Direct predictors of SMB and SMB mediated through to A1c

4	(2010) Osborn, C. et al.;	US Primary Medical Clinic patients. N=130 Adults> 18 w/T2DM	Predicted pathways linking Health Literacy, Self-Mgmt. and A1c	Health Literacy and Social Support effect on A1c outcomes	CFA, SEM, AMOS 7.0	Health Literacy has indirect effect A1c and Self-Mgmt... ↑Social Support = ↑ Self-Mgmt. & ↓A1c
5	(2010); Egede et al.;		Mechanism by which Depression influences Health Outcomes and Self-Mgmt. Behaviors	Is Depression Significantly Associated with Social Support and SMBG? Study Factors: Depression, Knowledge, Attitudes, Social Support: Outcomes: SMBG & A1c	SEM tested predicted Pathways. Depression has Indirect Effect on A1c with SMB as mediator	↑ Diabetes Knowledge, ↑Social Support = ↓ Depress. & ↑ SMBG. Exercise Diet & SMBG marginally associated with ↓A1c R ² = 24%)
6	(2011) Hartzler et al.;	COMBINE Study Research Group (2003); Secondary data analysis Pts. =1,383 randomized	Understandin g of Influences Mediating Intended Behavior Change – Alcohol Dependence	ΔSelf-efficacy as Mediator Between Therapeutic Bond and 1 Year Trmt. Outcomes was Significant	M-Plus (Mediation analysis) Products of Coefficient's approach	Small effect size; Self- efficacy Δ partially mediated Bond and Outcome Assoc.
7	(2011) Tierney et al., Meta Framework Analysis of Qualitative Research	Reviewed 3933 references; 20 out 32 Papers included in Meta Article review 1980+	Theory of Behavioral Change (Social Cognitive Theory) applied to Δ Heart Failure Pts. to ↑ Exercise	Self-efficacy and Outcome Expectancies Related to Exercise Adherence (Self-Mgmt.)	Qualitative: Framework Analysis System	Social Support, Cognitive Abilities, Affect (Emotional), and Adjusting to Δ →↑ SE→ increases activity levels
8	(2011), Annesi, JJ. Field Study of Severely Obese	116; Intention to Treat design.	SE and Mood were tested as Mediators between self- regulatory skill and outcomes (eating & exercise)	Self-Regulation is shown to be a "Trait-like personal characteristic." Volume of exercise & fruit/veggie consumption Predicts Weight Loss (R ² = .35)	Multiple Imputation, Mediation Analyses; Sobel Test, Multiple Regression	Negative Mood, not SE, mediated self- regulation and eating & exercise.

9	(2010); Hankonen et al.; Longitudi- nal study	US; GOAL Implementat ion Trial, 385 participants in 3 treatment models	Examined whether waist circumference changes are best predicted by personality traits (dispositional) or modifiable social cognitions (SE)	Increase in Δ SE reduced waist circumference over 12 mo. \uparrow SE, \rightarrow \uparrow SMB \rightarrow Outcomes/SE Mediated effect on Outcome. (Not personality traits)	SEM with FIML (3 models) with CFI, TLI and RMSEA for Model Fit indices	Δ SE $\uparrow \rightarrow$ \uparrow Exercise \rightarrow \downarrow Waist Circumference (-.26**)
10	(2011) DePalma, MT et al.,	US. Adults with Type 1 & 2 Diabetes. Internet survey of 46 Culturally Diverse Adults	Examined the relationship between judgments of responsibility for a past and present health behavior or event.	Type 1 rated “responsibility for disease onset lower than type 2 participants.	SEM Modeling, multivariate general linear modeling and regression techniques. Models: Responsibility , Anger, Blame, Social Support; Neg.SS; Pos. SS to SMBG Diet, Exercise, Smoke, SMBG	Responsibility for Disease onset was directly and significantly associated with Anger. Anger directly assoc. with Blame & Neg. Social Support. They were negatively associated with SMB. The 5 psychosocial variables explained 59% of the variance in SMB.
11	(2009) Diabetes Preventio n Program Research Group	US. Diabetes Prevention Program (DPP) Longitudinal Multi-Center Clinical Trials Study) 1996-2001, 3234 culturally diverse adults	High risk for pre-diabetes adults undertook interventions to delay the onset of diabetes or prevent it by lifestyle changes include diet and exercise.	Minimal lifestyle changes (7% loss of body weight, moderate exercise). Diet & Exercise can be MORE effective than medication (metformin)	4 intervention Groups - Coaches were provided to the life-style participants (arm-1).	Reduced risk of developing diabetes by 58% (lifestyle) compared to 31% in the medication group. Older participants reduced their risk by 71%.

12	(2009) Dailey, J. et al.	US Cross-sectional study using medical records and self-reported information Adult type 2 diabetes patients. 253 randomly selected outpatient clinic patients with A1c in past 3 months	Identify which barriers to Self-Mgmt. Behaviors are associated with problem behaviors & which barriers & behaviors are associated with A1c Control.	Cost was most common barrier to Self-Mgmt. Belief that T2 Diabetes is a serious problem (Affect) & Depression (Affect) were strongly assoc. with A1c. Married (Social) & Greater Self-Mgmt. SMBG & Meds were assoc. with A1c outcomes	Multi-variables Regression Model	2 of 8 Social Support were assoc. with A1c. 1 of 12 MD-pt. support were assoc. No assoc. with smoking & A1c. PHQ-9 was assoc. with A1c (Affect); SF12 Mental health assoc. with A1c. Confidence with SMB (Self-efficacy) was assoc. with A1c.
13	(2009) Williams et al.	United States; Longitudinal study; 2,973 Patients from Integrated Health System (2003-2004) and F/U in 2005 and 2006	Apply SDT model to Predict Medication Adherence, QOL and Clinical Outcomes on Patients with Diabetes	SDT model of health behavior fit the data.	SEM using AMOS 7.0. Measurement Model & Structural Model	Perceived autonomy-support from HC providers related to positive autonomous self-regulation for medication use. Perceived competence associated + with QOL and Med Adherence; & to A1c levels (-).
14	(2005) Williams et al.	US, HMO in Michigan, 2005, N=2973	Medication Adherence with type 2 diabetes by SDT Model of Health Behavior Method: Telephone & Mail Survey	↑Autonomy Support, ↑Competency, ↑Self-Regulation and ↑Self-management, Medication Adherence, A1C & QOL, LDL	SEM - Theoretical model was tested, X ² -IFI, CFI, TFI, RMSEA	Support →Self-Regulation (.42), Self-Regulation→Competence(.29), Competence → QOL (.35) Competence → Med Adherence (.15) Medication Adherence Competence → A1C (-.33) & LDL (-.31)

15	(2005) Williams et al.	UK/UKPDS: Longitudinal over 12 months 232 Patients w/type 2 diabetes. Outpatient Clinic and/or Community Hospital 1996-1999	Increased involvement in active D2M care yielded Increased level of A1C control thru 4 questionnaires over 12 months. Glycemic control thru D2M self- efficacy	SMB comparison between baseline HbA1c at 6 and 12 months	Qualitative Methods - Taped Conversations between Patients and Health Care Practitioner	Activation intervention effect on A1c was indirect. Active intervention ↑'d Active Patient Involvement. Active involvement had Direct & Significant Correlation to A1c Control.
16	(2004) Williams et al.	UK/UKPDS: Longitudinal Study with 232 Patients w/type 2 diabetes. Outpatient Clinic and/or Community Hospital 1996-1999	STD process model/theory through Self- Mgmt. Both HC QOL and TRSQ used. type 2 Diabetes Self- Mgmt. requires multiple complex behaviors be performed long-term in STD model for higher QOL.	SMB comparison between baseline HbA1c(T) 6 months(T2) 12 months(T4) and 18 months(T4)	Confirmatory Factor Analysis, SEM methods, Mediation and Model Fit	Perceived Autonomy Significant Effect on A1c over time.(1.75 (T1) to 1.50 at (T4))
17	(2011) Tucker, CM et al.	US 2009. 926 Culturally Diverse Adults. Participants divided into 6 Groups	MB-HSBI Validation study through Recruitment from churches, social clubs, YMCA.	Health of racially ethnic minorities and low-income individuals	Psychometric density in health behaviors: Self-efficacy	Motivators and Barriers to Self-Mgmt. survey had content validity. Correlation with SE and health-related goals in diverse population.
18	(2008) Brody et al.	US: 200 rural African Americans adults w/T2DB with 200 of their supporting adults/ family members	Home Interviews Conducted re: Quality of Relationships w/each other.	Structural equation modeling:	Social Support ↓ Morbidity among rural African Americans Adults with type 2 Diabetes	Results indicated Self- Mgmt. ↑ with Social Support. Social Support indirectly linked to A1c levels, mediated by ↑SMBG.

19	(1989 Landmark study). Glasgow R.E et al.	US: Lane Co. Oregon. 127 outpatients over 40 years with D2M	Study assessed relationship between diabetes knowledge, SE, skills & environmental support on self-mgt.	Multiple Regression Analyses.	DB self-care benefits from focus life-style behaviors, regiment-related expectations	Psychosocial factors improve prediction of Self-mgmt. (significantly) – beyond demographics. Vary across regimen areas (diet, exercise).
20	(2005) Maddigan, S. et al.	Alberta, Canada 393 Rural Adult Patients w/T2DB	To assess Patient Provider Relationship (PPR) & BMI on self-mgmt. (diet and exercise); how they relate to HRQOL	Theoretical Model tested using SEM; Time period data (LISREL using MLE)	Proposed PPR and BMI would indirectly affect HRQOL through self-mgmt. behaviors.	PPR and Exercise Adherence were key constructs in the model. HRQOL was + assoc. with exercise SM, which was related to +PPR. Diet Adherence assoc. with +PPR and no association w/HRQOL;
21	(2012) Renner, B. et al.	Finland study: Pajit-Hame province. 389 50-65 yrs. Adults w/elevated A1C & type 2 diabetes. Questionnaires on health cognition. T1-T3 tests, 3-20 months	Goal: Study health behavior changes using SCT in dynamic model (temporal assoc.) Aims to study adoption of & maintenance of exercise;	Self-efficacy for physical exercise change from static to dynamic view on behavior change	Health cognitions are amenable to change if adapting. Implications for Theory Development and Practical Intervention Research.	Phase specific & generic health cognition Δ 's during the intervention. Most Δ in those with low levels at beginning. Evidence for dynamic interplay between Δ 's in cognitions and behaviors.
22	(1991) Goodall, T. & Halford, W.	University of Queensland Critical Review of type 2 diabetes Self-mgmt. determinants & interventions	Variance in diabetic patients reported self-mgmt.	Social pressure, psychological stress, improved A1c control. Intervention effects are examined	Meta-Analysis of Determinants and Methods of promoting effective Self-Mgmt.	Concludes that self-mgmt. has been inadequately assessed. Interventions needed to improve SM.

23	(2004) DiMatteo, M.R.	UC- Riverside review of 122 studies correlating structural/fu nctional support w/patient medical regimen Adherence	Analysis of Structural or Functional Social Support with Patient Self- Mgmt.	Social Support; Family Cohesive- ness/Conflict; Marital Status; Living Arrangements of Adults	Meta- Analyses of Literature from 1948- 2001	Variables moderate effects. Practical support is most correlated to + Self-Mgmt. Cohesive Families have +1.74x self- mgmt. Marital Status & Living with another person ↑ Self-Mgmt.
24	(2010) Chiu, C. et al.	US study. Longitudinal 998 adults over age 51 w/type 2 Diabetes. US Health and Retirement Study.	Investigate the association between depressive symptoms and HbA1c control & the association's explains health behaviors	Depressive symptoms & Baseline & Follow-up Health Behaviors: exercise, body weight control, smoking Outcome: glycemic control	ANOVA; SEM with MLE; Correlations, SAS 9.1	Depressive symptoms & A1c was significant. Health Behaviors, exercise, BMI, Smoking, explained a sizable amount of assoc. depression & A1c
25	(2008) Sultan, S. et al.	Paris, France. Longitudinal (Baseline & 5 Years) 115 patients w/Type 1 Diabetes	Examine how anxiety & coping style can affect long-term A1c control.	Measured anxiety, coping style, anxiety, and glycemic control (A1c).	these factors compound and should be considered in designing follow-up and intervention with DB patients	Coping predicted A1c, especially if high in trait anxiety. Trait anxiety predicted A1c (modest)
26	(2007) Sacco, W. et al.	U -S. Florida Medical/Dia betes Center. 99 English- speaking adults w/T2DB	SDSCA questionnaire, multiple response format.	Adherence, Body mass index and Depression in adults w/T2DM	2 independent pathways by which BMI and Adherence can increase depression in T2DM patients.	1.higher BMI Equals poor Adherence and lower SE. 2.effect of higher BMI on depression is mediated by increased diabetic symptoms

27	(2005) Peyrot, M. et al.	DAWN Cross- Sectional Study. 5104 Randomly selected adults w/T1 or T2 DM and their providers (MD&RN's): from 13 countries: India, Europe, UK, US, etc.	To examine patient and provider reported psychosocial problems and barriers to Self-Mgmt. and Resources to assist in Dealing with them.	Data collected included: socio- cultural. diabetes duration; diabetes related stress; self- mgmt. (Diet, exercise, medication, SMBG, MD Visits) & Psychological Well-being (WHO-5 item index)	Self-Mgmt. was poor (Diet & Exercise); Diabetes worries were high. Providers lack skill, time, adequate referral resources for their patients	Patient self- mgmt. was deemed lower by providers than patient reports. 41% of pts. had poor psychological well-being. Providers did not have resources to manage the psychological problems & 10% only reported receiving intervention.
28	(2012) Inzucchi, S. et al.	Updated Position statement of ADA and EASD (European Association for Study of Diabetes)	Developed Recommendat ions for Patient- Centered Approach for diabetes patients to design individual care. Updated evidence- based clinical guidelines.	Patient-Centered Care defined. Pharmaceutical interventions; Patient Involvement & Effective Mgmt. Strategies for patient-centered approach	Joint Task Force Examined Recent Evidence for Anti- hyperglycemi c Therapy	T2 DB patients increased risk of CV morbidity and mortality. Aggressive management of these risks have greater benefits for DB patients
29	(2012) Critchley, Hardie & Moore	Australia: Randomized Control Trial; Sample of 307 Adults age 28-86, (mean=62) diagnosed with pre- diabetes and Healthy Living intervention	To Examine the psychological process of Lifestyle change for "at risk" pre- diabetics.	Measured weight and waist circumference 2 x in 6 months & 12 months. Self- report Questionnaires	Improved motivation for SE with group based programs to increase physical activity may provide cost- effective method of diabetes prevention	Significant ↑ in healthy eating and exercise, ↓ waist & ↓ weight, ↑ Motivation. Positive Mood, SE and Knowledge influenced activity levels. They ↑ knowledge & ↑ mood. Eating was not mediated ↑ in diet & exercise directly assoc. with Δ's in weight and waist.

Chapter 3 - Research Design and Methods

This dissertation used randomized trial study data with quantitative structural regression modeling to evaluate an a priori conceptual model of self-management behavior. This chapter describes the study's design, data source, sample selection and population, independent and dependent variables of interest, survey measures utilized, and the data analysis methodology.

Data Study Setting

Original study design. In 2008-2009, the HealthPartners Research Foundation designed and conducted a study called the *Journey for Control of Diabetes: The Interactive Dialogue to Educate and Activate (IDEA) Study*. The study's original design was a prospective longitudinal multisite randomized controlled trial with patients receiving differing types of education, group or individual, compared to a usual care (or no education) group.

Study setting. Health system adult patients with type 2 diabetes enrolled at two large medical groups, ABQ HealthPartners in New Mexico and HealthPartners Medical Group in Minnesota, were the target population for enrollment in the IDEA study between 2008 and 2009.

Study sample subject selection inclusion and exclusion criteria. Adult members with type 2 diabetes at the two large medical groups noted above were contacted for study enrollment based on assessment of eligibility criteria for the study. The IDEA study inclusion criteria included patients who had an A1c greater than 7% and no documented billing codes or self-reported group or individual

diabetes education in the last two years and the last year, respectively (Sperl-Hillen et al., 2011). In addition, the study participant had to be able to speak English, be between the ages of 18 and 85, and be able to travel to educational classes. Possible study participants were identified electronically in the care systems as meeting the eligibility criteria using diagnostic codes, central lab data, and claims. Exclusion criteria included visual and hearing impairment, cognitive impairment, age > 85, and inability to read English. After baseline participation, the patients were randomly assigned to one of the three study intervention groups using a computer-generated random allocation sequence at each site (Sperl-Hillen et al., 2011).

Original IDEA study timeline. The original study timeline began with baseline enrollment, randomizing subjects into three groups: 143 into usual care (UC), 243 into group education (GE), and 246 into individual education (IE). All subjects received psychosocial, self-efficacy, and self-management behavior surveys in person at baseline (T0). Surveys were subsequently mailed at approximately 3 months (T1), 6 months (T2), 9 months (T3), and 12 months (T4) post intervention, along with clinical and QOL outcomes data collected at baseline (T0), 6 months (T2), and 12 months (T4). Survey data collected by mail and electronic medical records abstraction were the methods used for the collection of data during the 12-month study period. Clinical data and results were updated from the electronic health record (EHR), if available, at baseline, six, and twelve months. (See Figure 3.)

Participants were given \$50 for completing a baseline enrollment visit and \$25 gift cards for the follow-up mailed surveys during the year. Enrollment required an in-person baseline visit. Study consenting occurred by trained study personnel.

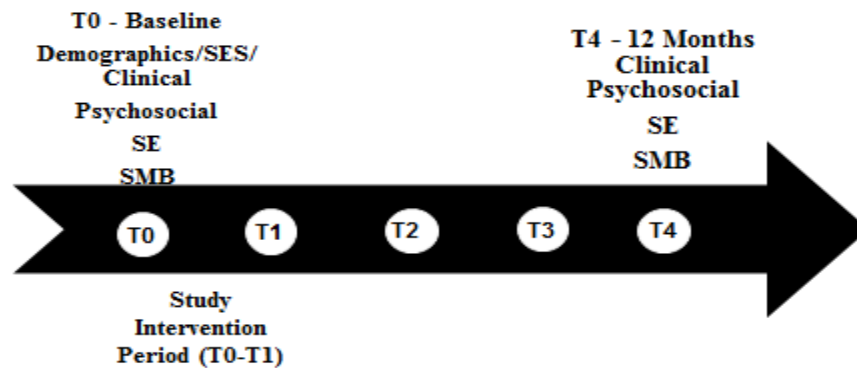


Figure 3. IDEA study timeline used in this research (T0 and T4) (additional data periods were collected at T1, T2, and T3 (approximately quarterly)).

The IDEA study data used in this study, was collected from patients who had not received individual DSMT within the previous year or group education within the past two years. Patients who qualified for the study were randomized to three groups: individual education (IE), group education (GE), or usual care (UC) as the control group. The study intervention was one of two education types: group education, which consisted of four two-hour sessions, or individual education, which consisted of three one-hour sessions with a certified diabetes educator (CDE). The group education was based on diabetes-specific topics using United States Diabetes Conversation Maps[®]. Individual education was based on needs

determined through assessment of the American Association of Diabetes Educators (AADE) Seven Self-Care BehaviorsTM. Attendance at educational sessions was recorded through the clinic's check-in process and captured electronically. While group and individual participants received education, usual care participants received no specific education intervention and served as the control group (Sperl-Hillen et al., 2011). This study showed, rather than originally hypothesized, that patients receiving individual education had significantly improved outcomes from patients receiving group education or usual care.

Data sample quality review. The use of secondary data required a detailed description of the data source(s) and uses that were available. The appropriateness of the data source was shown by the robust survey and clinical and behavioral data collected over the study period, using industry-specified reliable and valid instruments for the current study proposal. The validity and reliability of all relevant aspects of the secondary data sources were reviewed. Quality assurance methods, including cross-validation where possible, were used to review the quality of data sources. Linkages of the patient data longitudinally were deterministic, using unique patient identifiers with ethical precautions, and were outlined carefully. Patient confidentiality and privacy was maintained throughout the study.

Sample power analysis. Simultaneous effects of multiple sources of possible variation, statistical power to test the relationships of interest, and appropriateness of outcome measures were reviewed. Estimated power required to detect differences in A1c between time periods was needed (Huston, 1996). Data

from the Cochrane report supported the assertion that the clinical outcome, A1C, would be less amenable to change than the self-management behavior measures. As such, it was expected that the standardized effect sizes for each of these outcomes would be larger than for A1C. The original IDEA study sample power was developed to detect the predicted pattern of effects for A1C, so that the analysis would be powered at greater than 80% to also detect behavioral or health-related quality of life effects. A power analysis was performed to test the relative impact of using alternative educational interventions, the goal of the original study (Sperl-Hillen et al., 2010).

Sensitivity analyses were conducted to explore outliers, variables, and the robustness of the data. Overall, the predicted treatment effects used to calculate sample size for this study were considered conservative (Sperl-Hillen et al., 2010).

In structural equation modeling, sample size is an important aspect that is ideally considered in advance of data collection (Klein, 2011). As this research is using secondary data, this was not possible. This research is using a complex model design; thus there are more parameters and a larger sample size is required. When utilizing structural equation modeling, the rule of thumb for sample size is estimated at approximately a ratio of 5 to 20 participants per variable or parameter (Klein, 2011). This study utilized 25 unique variables collected during multiple time periods and thus had a recommended minimum sample size of 350–400 patients. Another recommended sample size rule of thumb is to have a minimum of 200 (preferably no less than 400, especially when observed variables are not

multivariate normally distributed) or to have 50 more than 8 times the number of variables used in the study ($50 + (70 \times 8) = 610$) (SAS/STAT User's Guide Version 8).

A rule of thumb concerning the relation between sample size and model complexity that has empirical support was referred to by Jackson (2003) as the $N:q$ rule and is applied when using maximum likelihood (ML) (Klein, 2011). A minimum sample size is determined in terms of the ratio of cases (N) to the number of model parameters that require statistical estimates (q). A sample size (N)-to-parameters ratio would be in the range of 10:1 to 20:1 (more ideal). As the $N:q$ ratio decreases, the trustworthiness of the results decreases as well (Klein, 2011). The IDEA study provided a minimum sample size for the secondary data analysis proposed to explore the aims set forth in this proposal.

Sample selection. Sample selection issues were addressed by comparing study subjects who participated to those who chose to be nonparticipants. An analysis of the 939 accessed for eligibility showed 309 were excluded; 172 met exclusion criteria and 137 did not show up for the enrollment visit without a reason specified.

An analysis was conducted on the limited study data of the “non-participants” to determine if any significance in differences in patient characteristics of study participants and nonparticipants. Of the 7,977 non-enrolled study eligible patients, their mean age was $61.8 (\pm 12.4)$ years (min-max was 27-86 years of age); the A1c baseline value mean was 8.2 ± 1.5 and ranged from 7.0 to 18.4; 47.7% were female

and the site of enrollment was 67.7% HP and 32.3 from LCF. The follow-up A1c analysis was available in 6,212 of the initial nonenrolled group (and had a 22.1% non-available rate compared to a mean of 17.8% for those who participated). It appears that those in the study may have a stronger interest or more time for their diabetes self-management as they followed up with A1c testing at a significantly higher rate than those who were eligible but did not enroll.

Protection of human subjects. The study engaged only persons who had agreed to and consented to be part of the Journey for Control of Diabetes IDEA Study. This research project conducted an analysis using secondary data and did not include any direct or indirect contact with human subjects. Exemption from the University of Minnesota Institutional Review Board was awarded prior to the use of the secondary data. In addition, HealthPartners Research Foundation secured HPF Institutional Review Board approval to add this researcher as an approved investigator with secure access to the de-identified IDEA study data. Specifically, the data use agreement prohibited any attempt to identify individuals in the dataset or publish any results with a cell size smaller than 10, as that could potentially allow for individual identification. Any individual identifiers remained solely on encrypted, password-protected computers in locked offices. Data security procedures were approved by the IDEA study. The project did not involve more than minimal risk to individuals in the dataset and did not adversely affect the subjects' rights or welfare.

Data Sources and Measurement

Data collection procedures. Data sources included measurements collected at an in-person baseline enrollment visit, passive surveillance of electronic health record (EHR) observations, and responses to mailed surveys in the baseline and post intervention period. Multiple psychosocial, clinical, and demographic measures were identified from interview, self-report surveys, and electronic health record data.

Study staff measured height, weight, waist circumference, and blood pressure at the baseline visit. They then calculated body mass index (BMI) and had participants complete the Literacy Assessment for Diabetes (LAD) at the baseline visit. For other clinical variables, the analysis used the latest value (e.g., A1c) observed in the EHR in pre and follow-up evaluation periods. Educational contact hours were recorded through the clinic's check-in process and captured electronically during the first quarter.

Psychosocial and behavioral measurements were conducted through self-report surveys completed at the baseline visit and follow-up mailed surveys at approximately 3, 6, 9, and 12 months after each participant's last scheduled educational session (See Figure 3). The comprehensive variables measured included those outlined in more detail below.

Response rate. Of the 5,627 total eligible patients with type 2 diabetes and A1c's ≥ 7 in the two large medical groups, a final sample of 623 patients were enrolled in the study, exceeding the goal (Beaton et al., 2010). The 623 patients

participated in the baseline data collection process. During the course of the twelve-month study, a total of fifteen died during the study period and one withdrew.

These patients were removed from the analysis, leaving 607 (97%) patients in the study. There were 512 respondents in Time 2 and 513 respondents in Time 4 (see Table 3).

Due to the requirement of complete data for structural equation modeling, the sample size was reduced to include only those who completed at least two of three study periods (baseline, T2, and T4). Further analysis showed that of study participants who completed the survey instruments in at least two out of the three time periods under study (T0, T2 and/or T4), 564 or 92.9% met the criteria. Two hundred eight (208), or thirty-four percent (34%), of the 607 study participants had one hundred percent (100%) complete data throughout all three time periods of the study. Table 3 provides details of the sampling approach and the accrual of patients in the original IDEA study.

Table 3

Possible and Actual Study Recruitment Numbers (Sperl-Hillen et al., 2010)

HealthPartners:	Minneapolis	Lovelace	TOTAL
Total number of diabetes patients identified - via 2 ICD9 codes - A1c >7% in the last 6 months, - No diabetes education in the last 2 years	3,500	3,120	6,620
POSSIBLE STUDY PATIENTS (after all exclusions for Type 1, gestational and A1c levels,	2,975	2,652	5,627

etc.)			
Scheduled for enrollment			760
Enrolled in study	337	286	623 (82%)
Randomized to Group Education (GE) , Individual Education (IE) & Usual Care (UE)			UC = 134 IE = 246 GE= 243
Number withdrew or died	Withdrew =1 Died = 8	Withdrew=0 Died=7	Withdrew =1 Died =15
Actual number enrolled (after died/withdrawals)	330	277	607
Completed T0 and T2 and /or T4 time periods	317 (56.2%)	247 (43.8%)	564/607 (92.9%)
100% complete data for T0 & T4			495 (T0) 225 (T0 & T4)
T4 completed surveys	295/513 (57.5)	218/513 (42%)	513/564 (91%)
T4 Missing	42 (12.5)	68(23.8)	110/513 (19.5%)

The overall response rate was 11% and it satisfied the power requirements as well as the resources available to conduct the study. An article outlining the recruitment methodology issues was published by the IDEA study team, which noted:

- a. This is a similar participation rate compared to what has been seen for other comparable clinical trials given the recruitment methodology used;
- b. The letter of invitation to participate represented it as a research study (not education recommended by their doctor or care team). Education may be considered a low benefit for patients also;

- c. The interventions were a large time commitment for patients, as they had to attend a consenting and baseline visit to enroll at a location that was not considered convenient for many patients, and;
- d. The use of patients with sub-optimally controlled diabetes may show that they are not as interested in improving health behaviors (Beaton, Sperl-Hillen, & Worley, 2010).

Survey Measurement Instruments—Assessment Tools

The summary of the major survey instruments used in this research for measurement is described below in Table 4. The following section describes in more detail the sources of the instrument and the research showing the instrument as reliable and valid. Specifically, these instruments were selected for their use in validated research on patients with type 2 diabetes.

Table 4

Major Survey Instruments Used in the IDEA Study

Variable Name and Survey Domain	Survey Instrument Description
PSYCHOSOCIAL FACTORS	
Affect: Depression (PHQ-9 & PHQ-2)	Patient Health Questionnaire (PHQ-2 and PHQ-9). A two-item and nine-item severity of depression measurement module (Kroenke et al., 2001; Polonsky et al., 2005).
Affect: Diabetes Distress (PAID)	Problem Areas in Diabetes (PAID). A 2-item measure of diabetes-specific emotional distress scaled 0–100 with higher scores indicating greater distress (Welch, Jacobson, Polonsky, & Anderson, 1997).
Affect: Attitudes	Diabetes Care Profile (DCP) section

	to evaluate positive and negative attitudes. Each component involves the mean of a set of questions scaled 1-5 (Fitzgerald et al, 1996; Michigan Diabetes Research and Training Center, 1998).
Knowledge: Understanding of Care & Importance of Care	Diabetes Care Profile (DCP) sections to assess understanding, importance of care, and care ability. Each component involves the mean of a set of questions scaled 1–5 (Fitzgerald et al., 1996; Michigan Diabetes Research and Training Center, 1998).
Knowledge: Literacy Assessment-Diabetes (LAD)	Literacy Assessment Tool-Diabetes (LAD) is a validated measurement tool developed to assess the health literacy of persons with diabetes (Nath et al., 2001).
Diabetes Social Support	Diabetes Care Profile (DCP) sections to assess social support needs, support received, and support attitudes (feeling supported by family and friends). Each component involves the mean of a set of questions scaled 1–5. (Fitzgerald et al., 1996; Michigan Diabetes Research and Training Center, 1998)
SELF-EFFICACY FACTORS	
Self-efficacy: Diabetes Empowerment Scale–Short Form (DES-SF)	Diabetes Empowerment Scale – Short Form (DES-SF). The average score of eight items (value ranging from 1–5) measuring self-efficacy in people with diabetes (Michigan Diabetes Research and Training Center, 1998).
Care Ability & Self-Care Management	Diabetes Care Profile (DCP) sections to assess self-reported care ability and self-care management. These components involve the mean of a set of questions scaled 1–5 (Fitzgerald et al., 1996; Michigan Diabetes Research and Training Center, 1998).
SELF-MANAGEMENT FACTORS	

Nutrition: Recommended Food Score (RFS)	Recommended Food Score (RFS). A summary score ranging from 0–23 of 23 items recommended by current dietary guidelines consumed at least once per week (Kant et al., 2000).
Physical activity—Behavioral Risk Factor Surveillance System (BRFSS)	Behavioral Risk Factor Surveillance System (BRFSS). Method: Physical activity score sections 17.3, 17.4, 17.6, and 17.7 (minutes per week of vigorous or moderate level activity) (CDC, 2007).
Self-Monitored Blood Glucose Testing (SMBG)	Self-report question on frequency of daily testing (Harris et al., 2000).
Tobacco Use (Audit-C)	Tobacco use was measured by the Alcohol Use Disorders Identification Test (Babor et al., 2006) Yes/No response to “Have you smoked or used tobacco products in the last 30 days?”

PHQ-9 and PHQ-2. A number of validated self-administered questionnaires have been developed to assess depression. The PHQ-9 is an instrument based on *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) criteria and used by clinicians to assess depressive symptoms and evaluate their severity (Polonsky et al., 2005; Kroenke et al., 2001; Belton et al., 2008). Based on a diagnostic meta-analysis, the PHQ-9 has demonstrated usefulness as a screening tool for depression with acceptable reliability, validity, sensitivity, and specificity (Gilbody et al., 2007). The nine-item Patient Health Questionnaire depression screening tool (PHQ-9) was validated to serve as a depression severity measure and a diagnostic instrument for the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV) section on depressive disorders (Kroenke, Spitzer, & Williams, 2001).

A shorter version, a two-item Patient Health Questionnaire screening instrument, was developed using the first two questions from the PHQ-9 to inquire about the frequency of depressed mood and to determine if the full PHQ-9 screening instrument was needed to further measure symptoms of depression. The PHQ-2 is a validated screening instrument that inquires about the frequency and severity of depressed mood and is used to determine if the full PHQ-9 screening instrument is needed to further measure symptoms of depression (Kroenke et al., 2001; Kroenke, Spitzer, & Williams, 2003; Polonsky et al., 2005). The PHQ-2 instrument demonstrates construct and criterion validity for depression screening and has been used extensively in patients with type 2 diabetes (Kroenke, Spitzer, & Williams, 2003; Polonsky et al., 2005).

PAID (Problem Areas in Diabetes). The Problem Areas in Diabetes (PAID) scale is the most widely used measure to assess diabetes-specific emotional distress (Polonsky et al., 1995, Polonsky & Welch, 1996; Welch, Jacobson, & Polonsky, 1997). The PAID scale is a validated and highly reliable distress survey tool. Comprising 20 items, the scale produces a total score ranging from zero to 100, with higher scores indicating greater distress. The respondents were asked to rate “How much of a problem” on a five-point scale with options from “0 = not a problem” to “4 = serious problem,” they find in each of the 20 issues raised. Examples of items are (i) Worrying about the future and the possibility of serious complications, and (ii) Feeling scared when you think about living with diabetes. This instrument has been used extensively in diabetes research. Its responsiveness

has been tested, supporting its sensitivity to change over time (Welch et al., 2003). Previous research (Welch et al., 1997) supports using a total score (with one general 20-item factor), but both two-factor and four-factor solutions have been reported also (Sigurdardottir & Benediktsson, 2008; Snoek et al., 2000).

The tool measures 20 items of emotional adjustment to life with diabetes that potentially may be useful to clinicians caring for patients with diabetes. PAID has demonstrated high internal reliability, construct validity, and discriminant validity (Welch et al., 1997). The PAID scores have shown strong correlation with standardized psychological distress measures, health-related cognitions, social support, and self-efficacy (Rosenstock, 1985; Stretcher, DeVellis, Becker, & Rosenstock, 1986). The PAID instrument has been used extensively in diabetes research. Its responsiveness has been tested, supporting its sensitivity to change over time (Welch et al., 2003). Previous research supports using a total score with one general 20-item factor (Welch et al., 1997).

A review of seven studies evaluating the utility of the PAID indicated internal reliability remained high ($\alpha = .90$), and test-retest reliability was found to be adequate ($V = .83$). This same study also found the PAID score was correlated with a variety of theoretically relevant constructs such as general emotional distress, depression, diabetes self-management, diabetes coping, and health beliefs (Welch et al., 2003).

Diabetes Care Profile (DCP). The diabetes care profile (DCP) is a reliable and valid self-administered instrument designed to measure the psychosocial

(affect), social, and educational (cognitive) factors related to diabetes care and its treatment. Based on the Health Belief Model, the DCP instrument was developed to better understand health behaviors by measuring social and psychological factors important to a patient's ability and willingness to provide self-management (Glasgow & Osteen, 1992; Janz & Becker, 1984; Rubin & Peyrot, 1992). The DCP contains questions in seven sections to assess four major constructs from the HBM: perceived severity of the disease, perceived susceptibility to complications, benefits of self-management behaviors, and barriers to self-management behaviors (Fitzgerald et al., 1996; Michigan Diabetes Research and Training Center, 1998). Within the DCP are 14 scales representing the major psychosocial factors included in this study, including affect (positive and negative attitudes), knowledge (understanding of disease and importance of care), social (social support needs, support received) and self-efficacy (care ability and self-care management).

Evidence of construct validity can be ascertained from correlations of the DCP scales to the physiologic measure of glycosylated hemoglobin (A1c). A1c is a blood test that measures a patient's average blood glucose level for the past two to three months. Scales designed to measure self-care ability, self-care adherence, and control problems should correlate with level of metabolic control (Fitzgerald et al., 1996). The DCP showed that patients with insulin-dependent diabetes (IDD) had the best understanding of their self-care, but they also stated more difficulty in following their care regimen (insulin ... the medical scales barrier) than patients with non-insulin-dependent diabetes (NIDD). Patients with IDD using insulin

reported the fewest problems with self-monitoring (the monitoring barriers scale). Diabetes had less impact on the social and personal life of patients with NIDD not using insulin than patients using insulin (Fitzgerald et al., 1996).

The DCP's validity was supported, and hypothesized differences were confirmed. For example, it was expected that the more severe the disease, the greater the difficulty patients would experience with controlling their diabetes. Self-reported control problems were the greatest for patients with insulin-dependent diabetes (IDD), followed by patients with non-insulin-dependent diabetes (NIDD) who are using insulin, and the fewest problems by patients with NIDD not using insulin. The DCP is sensitive to differences between all three groups (Fitzgerald et al., 1996).

Correlations between DCP and the Center for Epidemiologic Studies depression scale (CES-D) were also found (Radloff, 1977). As levels of depression increased, patients reported greater difficulty controlling their diabetes, and greater impact of diabetes on their personal and social lives. Two correlations with CES-D were not hypothesized, but were found in reviewing the data. The scale was negatively correlated with self-care management and positively correlated with the scale of monitoring barriers. Lower depression scores were correlated with higher self-care adherence and fewer problems with self-monitoring.

The social provisions scale also correlated with understanding of self-management practice (Fitzgerald et al., 1996). The more positive patients are about available social support, the better is their understanding of self-care.

Furthermore, in DCP scale correlations with A1c levels, the three scales that dealt directly with self-care (control problems, self-care ability, and self-care adherence) are correlated in the expected direction.

The DCP has been validated as an instrument for use as a baseline measure in intervention studies. Although these studies support the research use of the DCP, further research is needed to establish its utility in clinical settings. The scales that focus on self-care management, barriers, control, and benefits may be useful in patient care (Fitzgerald et al., 1996).

Health Literacy Assessment (LAD). A validated Health Literacy Assessment tool for persons with diabetes was utilized to assess their ability to read and understand health literacy (Nath et al., 2001). The Literacy Assessment–Diabetes (LAD) tool is a reliable and valid instrument for measuring literacy in adults with diabetes. The LAD tool’s reliability and validity was tested against two other health literacy tools using a test-retest study design involving 203 patients with diabetes (Nath et al., 2001). It is easy to administer and measures a patient’s ability to understand terms they will be hearing during their physician visits and self-care learning educational sessions. Most of the words are at a fourth-grade reading level, with some using a sixth through sixteenth grade level (Nath et al., 2001).

The diabetes specificity of the LAD tool serves two purposes: (1) to provide specific assessment for vocabulary that is unfamiliar to most patients, and (2) to provide a nonthreatening means of assessing overall literacy, since patients would

not be expected to know diabetes terms at the time of their diagnosis. The LAD showed high concurrent validity with other health literacy tools, as demonstrated by a correlation coefficient of 0.81 with the wide range achievement test-3 (WRAT3) and 0.90 with the Rapid Estimate of Adult Literacy in Medicine (REALM). It has test-retest reliability with an interclass correlation coefficient of 0.86 (Nath et al., 2001). It was not determined whether screening and identifying patients with poor literacy has an effect on later patient-clinician relationships or improves patient outcomes, though identifying low literacy would signal a need for improved communication.

Diabetes Empowerment Scale (DES). The Diabetes Empowerment Scale–Short Form (DES–SF) takes the average score of eight items (values ranging from 1–5) measuring self-efficacy in people with diabetes (Michigan Diabetes Research and Training Center, 1998). The structure of the DES was based on earlier work in patient empowerment, and the DES subscales were derived from the earlier behavior change model. Two remaining subscales (Managing Stress and Obtaining Psychosocial Support) were added to the DES because these have been identified as major barriers or facilitators of behavior change and psychosocial adaptation to diabetes. The pilot version of the DES informed the ultimate tool. Validity was established when DES subscales were compared with two previous validated subscales of the Diabetes Care Profile (DCP). Factor and item analyses provided subscales that were coherent, meaningful, and had an acceptable coefficient. Analyses resulted in a 28-item DES ($\alpha=0.96$) with three subscales: (1) Managing

the Psychosocial Aspects of Diabetes ($\alpha=0.93$), (2) Assessing Dissatisfaction and Readiness to Change ($\alpha = 0.81$), and (3) Setting and Achieving Diabetes Goals ($\alpha = 0.91$). The DES instrument was originally studied using a mailed survey to patients involved in various Michigan Diabetes Research and Training Center outreach programs. A Pearson correlation matrix was used to examine relationships among the DES subscales. Conclusions were that the primary purpose and value of the DES is as a measure of psychosocial self-efficacy viewed as an outcome of successful educational and clinical interventions (Anderson, 2000).

Nutrition—Recommended Food Score (RFS). The Recommended Food Score (RFS), a 23-item scale instrument based on self-report of consumption of foods recommended by current dietary guidelines, was administered to measure food intake and validated in 2000 (Kant et al., 2002). The instrument was developed from phase two of a prospective cohort study of breast cancer screening, the Breast Cancer Detection and Demonstration Project (BCDDP), sponsored by the National Cancer Institute and the American Cancer Society. A total of 42,254 women completed the food frequency questionnaire portion of the survey, and the median follow-up was 5.6 years. Data was collected using baseline telephone interviews and a secondary follow-up with mailed questionnaires. The RFS instrument was based on reported consumption of recommended foods according to current dietary guidelines. The Cox proportional hazards regression examined the independent association of the diet quality measure with mortality in the presence of covariates, with follow-up time as the underlying time metric. Baseline variables included age,

race, education level, BMI, smoking status, history of cancer, heart disease, or diabetes, menopausal hormone use, and physical activity level. The RFS was categorized into quartiles based on its distribution in the analytic cohort. The Recommended Food Score was inversely associated with all-cause mortality. Subjects in the upper quartiles of the RFS had relative risks for all-cause mortality of 0.82 in the second quartile, 0.71 in the third quartile, and 0.69 in the fourth quartile, compared with the lowest quartile (Kant et al., 2000).

Physical Activity-Behavioral Risk Factor Surveillance System (BRFSS).

In 1993, the Centers for Disease Control and Prevention developed a measurement tool for assessing Health-Related Quality of Life (HRQOL) called the Behavioral Risk Factor Surveillance System (BRFSS). The data collected through such surveillance can inform health policy, planning, and practice and help states track progress toward improving quality of life. These measures were developed to reflect dysfunction and disability associated with chronic disease and other health problems.

In this study, physical activity (PA) was measured using the physical activity sections 17.3, 17.4, 17.6, and 17.7 of the Behavioral Risk Factor Surveillance System (BRFSS) survey developed by the Center for Disease Control and Prevention (CDC, 2007). The validated four-question BRFSS measures specifically for physical activity were developed using telephone surveys to monitor health risk behaviors among adults. 102,263 respondents in 49 states participated. They were asked about personal behaviors such as physical activity, weight control,

alcohol consumption, and smoking that result in the most significant health and safety problems. A fixed set of core questions was asked each year, and a rotating set of questions is asked during specified years. The validity of the conceptual model was examined using the earliest available 1993 data for the four questions from more than 2,900 BRFSS respondents in six states (CDC, 2007).

Self-monitoring of blood glucose (SMBG). Self-monitoring of blood glucose (SMBG) testing was designed to investigate the effect of this intervention on glycemic control in poorly controlled, insulin-naïve, type 2 diabetic patients compared with enhanced usual care (Polonsky et al., 2011). The Structured Testing Program (STEP) is a 12-month, multicenter comparison between patients with A1C $\geq 7.5\%$ and an active control group. The poorly controlled non-insulin-treated group used structured SMBG along with quarterly clinic visits that focused specifically on diabetes management, free blood glucose meters and strips, and office point-of-care A1C capability. Patients were from small and large primary care practice sites in the eastern US. Patient visits occurred at initial screening and baseline, followed by visits at months 1, 3 6, 9, and 12. Investigators recorded or collected demographics, relevant medical history, physical exams, lab samples, and documented current medications. Of 770 patients screened, 483 took part in and completed the study. Patients completed the STEP questionnaire, which included self-care measures, diabetes-related distress, and depression. The primary measure was the change in A1C from screening to 12 months. The results showed that structured SMBG contributes to significant improvement in glycemic control in insulin-naïve type 2

diabetes patients compared with patients who did not receive structured SMBG (Polonsky et al., 2011). SMBG frequency testing was one question used based on work from the research and validation of a structured interview for the assessment of diabetes self-management (Harris et al., 2000).

AUDIT-C (alcohol and tobacco use). Alcohol and tobacco use was assessed with a validated instrument called the Alcohol Use Disorders Identification Test (AUDIT-C) (Babor et al., 2006). The AUDIT-C is a three-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of a 10-question AUDIT instrument (Bush et al. 1998). A survey question on tobacco use was identified, using the identical question on alcohol use from the AUDIT-C instrument.

Study Latent and Observable Measures

The proposed conceptual model described in Chapter 1 is reviewed in more detail regarding the observed measures used to develop latent variables for the psychosocial factors of affect, knowledge and diabetes social support, and self-efficacy. The detailed observed variables used to construct latent factors theorized to better predict self-management behaviors are described in more detail below and are shown in Figure 4.

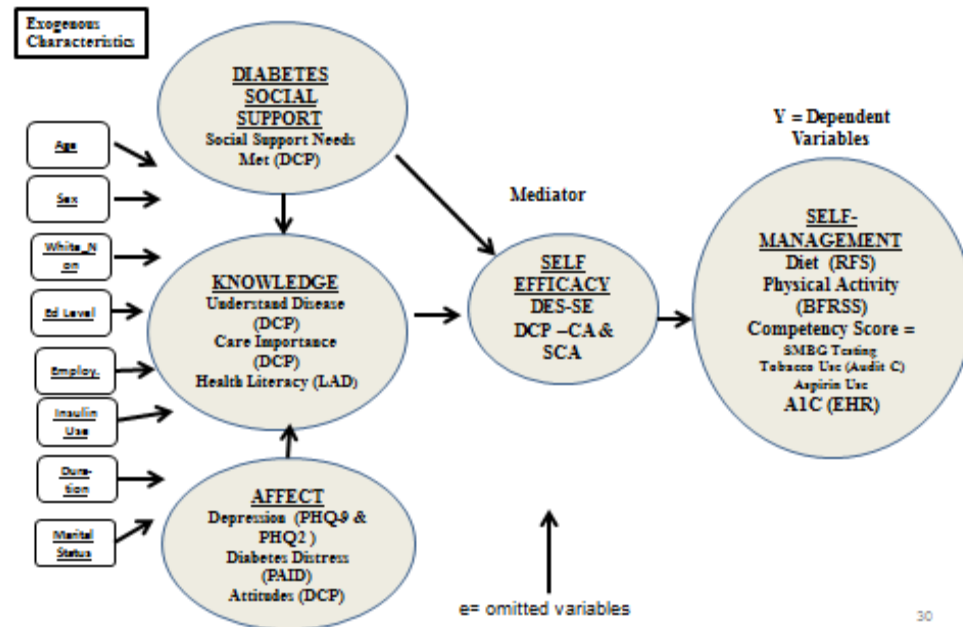


Figure 4. A priori conceptual model showing the observed measurement instruments being utilized for each latent construct.

Diabetes social support measures. The latent construct of diabetes-related social support was measured using the diabetes care profile (DCP) social support sections, including understanding of the help and support needed or wanted from family or friends (support needs) and help and support actually received (support received) (Michigan Diabetes Research & Training Center, 2008; Fitzgerald et al., 1996). Correlations of previously validated scales to specific DCP scales support concurrent validity. Although the focus of DCP is on diabetes, patient responses correlated in the expected direction with more general scales of social support and well-being.

This research had access to two functional social support measures, marital status and the number of others living in household, from a self-report survey at baseline. The marital status of the individual was measured based on the self-report during the baseline demographic survey and was not updated during the remaining survey period. These measures both have face validity within sociology as functional social support mechanisms. Marital status was used as an exogenous variable in the study.

Affect measures. In this study, the latent construct of affect was theorized as being measured using three distinct emotion and mood variables: a) depression; b) diabetes-related distress; and c) attitudes. Three validated self-report questionnaires were administered to study participants including:

Depression (PHQ-9 and PHQ-2). The Patient Health Questionnaire (PHQ-9), a nine-item screening tool for depressive symptoms, was administered at baseline. PHQ-9 was scored as a continuous variable (range of 0–4 for the continuous score), and a categorical variable was developed using no depression (scores 0–4); mild (scores 5–9); and moderate depression or greater (scores ≥ 10). The PHQ-2 questionnaire was administered at baseline (T0) and twelve-month (T4) follow-up surveys (Sperl-Hillen, 2011). The respondents were asked to rate how often they had been bothered by the following two problems in the past two weeks on a four-point scale, with options from “0 = Not at all” to “4 = Nearly every day.” The two items included on the PHQ-2 survey are (i) Little interest or pleasure in doing things?; and (ii) Feeling down, depressed, or hopeless? The PHQ-9 adds

seven additional questions to those in the PHQ-2. Examples of questions are (i) feeling bad about yourself, or that you are a failure or have let yourself or your family down; and (ii) thoughts that you would be better off dead or hurting yourself in some way. Although initially intended to be administered at six months, neither the PHQ-2 nor PHQ-9 were administered at T2, but the PHQ-2 was available in T4.

Diabetes-related stress (PAID). The PAID scale, comprising 20 items in this survey, produces a total score ranging from 0 to 100, with higher scores indicating greater distress. During one of the IDEA survey periods, one of the 20 PAID questions was omitted, and the 19 responses were scaled to 100. The respondents were asked to rate how much of a problem, on a five-point scale with options from “0=not a problem” to “5=serious problem” they found in each of the 20 issues raised. Examples of items on the PAID survey include (i) Worrying about the future and the possibility of serious complications, (ii) Feeling scared when you think about living with diabetes, and (iii) Feeling discouraged with your diabetes treatment plan.

Negative and positive attitudes (DCP). The section of the Diabetes Care Profile (DCP) focusing on assessing positive and negative attitudes was used to measure attitudes toward diabetes for each participant. The respondents were asked to rate how much they agreed or disagreed with the statement on a five-point scale, with options from “0=strongly disagree” to “5=strongly agree they found in each of the 10 statements. Examples of negative and positive items on the “attitude” section of the DCP survey include (i) I am afraid of my diabetes, (ii) I find it hard to do all

the things I have to do for my diabetes, and (iii) I can do just about anything I set out to do.

Knowledge measures. The latent construct of knowledge was measured using two instruments and three measures, including the diabetes care profile (DCP) knowledge sections measuring understanding of disease management practice and the importance of self-care. One additional survey of the individual patient's health literacy-diabetes (LAD) was used to test the ability to learn health-related diabetes concepts. These survey instruments are discussed in more detail in the following sections.

Understanding of disease—Diabetes Care Profile (DCP). The DCP Understanding of Disease section focused questions on how well a patient understands diabetes (knowledge). The results from this section were used as one of four observed indicators to form the latent construct of knowledge. Examples of items on the DCP survey section on understanding include “How do you rate your understanding of (i) coping with stress, (ii) the role of exercise in diabetes care, and (iii) prevention of long-term complications of diabetes.”

Importance of self-care—Diabetes Care Profile (DCP). The DCP section used to assess knowledge included the section assessing the importance of care. Examples of items asked on the DCP importance of care survey section include (i) I think it is important for me to keep my blood sugar in good control, (ii) I think it is important for me to keep my weight under control, and (iii) I think it is important for me to do the things I need to do for my diabetes (diet, medicine, exercise, etc.).

Health Literacy (LAD).

The concept of health literacy has been developed specifically for adult patients with diabetes. The LAD instrument uses word recognition of commonly used medical terms necessary to understand with diabetes care. By testing understanding of the three lists of words, it is a way to detect reading comprehension of medical words needed for understanding diabetes care and is scored by adding the correct word selection. Scoring totals are categorized into 4th, 5th-8th or 9th or greater grade reading levels. Words range from easy (i.e. pill) to harder (endocrinologist).

Self-efficacy. The latent factor of self-efficacy was formed using three indicators, the diabetes empowerment scale–short form (DES) and two self-report sections on the DCP, care ability and self-care management. These measurement instruments have been validated for use with patients with type 2 diabetes. Each instrument is discussed in more detail below.

The Diabetes Empowerment Scale–Short Form (DES-SF). The concept of perceived self-efficacy has been developed specifically for patients with diabetes. The instrument used to measure self-efficacy is the Diabetes Empowerment Scale–Short Form (DES-SF) in the IDEA study. It is a validated eight-item scale measuring self-efficacy in people with diabetes (Michigan Diabetes Research and Training Center; Anderson et al., 2003). The scoring of the DES is straightforward and based on completed items. An item checked “strongly agree” receives 5 points; “agree” 4 points; “neutral” 3 points; “disagree” 2 points; and “strongly disagree”

receives 1 point. An overall numerical score for the DES is calculated by adding all of the item scores and dividing by 8 (Michigan Diabetes Research and Training Center, 1998).

The DES score is shown in a continuous variable. The survey questions asked the respondents to rate their response to eight statements on a five-point scale, with options from “1=strongly agree” to “5=strongly disagree.” Examples of items on the DES survey include (i) In general, I believe that I am able to turn my diabetes goals into a workable plan, (ii) In general, I believe that I can find ways to feel better about having diabetes, and (iii) In general, I believe that I know what helps me stay motivated to care for my diabetes.

Care ability–Diabetes Care Profile (DCP). The DCP section, self-reported self-care ability, was used as an indicator to assess self-efficacy of the study participant. The respondents were asked to rate their self-care ability on a five-point scale with options from “0=strongly disagree” to “5=strongly agree,” on four key abilities. Examples of items on the DCP survey responding to “I am able to” included (i) keep my blood sugar in good control, (ii) keep my weight under control, (iii) do the things I need to do for my diabetes (diet, medicine, exercise etc.), and (iv) handle my feelings (fear, worry, anger) about my diabetes.

Self-care management Ability–Diabetes Care Profile (DCP). The DCP section, self-reported self-care management ability, was used as an indicator to assess self-efficacy of the study participant. The respondents were asked to rate their actual “doing” of self-care management activities on a five-point scale with

options from “0=strongly disagree” to “5=strongly agree,” on four key self-care abilities. Examples of items on the DCP survey responding to “I do” included: (i) keep my blood sugar in good control, (ii) keep my weight under control, (iii) do the things I need to do for my diabetes (diet, medicine, exercise etc.), and (iv) handle my feelings (fear, worry, anger) about my diabetes.

Self-management behaviors & A1c—dependent variables. The proposed conceptual model used key health behavioral factors as dependent variable measures for self-management behaviors and A1c. The self-management behaviors and A1c were measured using baseline self-report scores from validated and reliable survey instruments. The measures included dietary self-care, physical activity, self-monitoring of blood glucose levels, tobacco use, and aspirin use. Electronic health record information was collected to match to and follow the A1c values of the study participants.

The self-management behaviors (SMB) under study have been measured and shown to have significant associations with improved diabetes outcomes, including dietary habits, physical activity, self-monitored blood glucose (SMBG) testing, and tobacco use. Self-reported behaviors regarding dietary intake, exercise levels, and frequency of SMBG testing were collected using the following instruments: 1) dietary self-care—Recommended Food Score (RFS); 2) physical activity: levels of physical activity (BRFSS); 3) frequency of self-monitoring blood glucose (SMBG) as self-reported; 4) tobacco use from the Audit–C survey; and 5) daily aspirin use as self-reported.

Food intake (RFS). The survey tool used to measure food intake was the Recommended Food Score (RFS), a 23-item scale instrument based on self-report of consumption of foods recommended by current dietary guidelines. The respondents were asked to rate which of 23 foods had they eaten at least once in the past seven days on a two-point scale, with options of “0 = no” to “1 = yes.” Examples of items on the RFS survey include (i) cantaloupe, (ii) broccoli, and (iii) spinach.

Physical activity or exercise (BRFSS). The survey tool used to measure physical activity was a section of the BRFSS noted above, using a four-item questioning instrument based on self-report of physical activities by current physical activity guidelines. Physical activity (PA) was measured using the physical activity sections 17.3, 17.4, 17.6, and 17.7 of the Behavioral Risk Factor Surveillance System (BRFSS) developed by the Center for Disease Control and Prevention (CDC, 2007).

The respondents were asked to rate how often and for how long they did vigorous and moderate activities during a usual week, using multiple-point scales with options of 0–7 days in a week. Several categories were developed for the minutes spent in physical attitude including a low of 10–15 minutes per day to 121 or more (or “I do not do vigorous activities for at least 10 minutes at a time.”). The same questions were asked for moderate activities. Examples of items on the RFS survey include (i) On how many days and minutes during a usual week do you do vigorous (moderate) activities for at least 10 minutes at a time, such as running,

aerobics, heavy yard work, or anything else that causes a large (small) increase in your breathing or heart rate?’ and (ii) On days when you do vigorous (moderate) activities for at least 10 minutes at a time, such as brisk walking, bicycling, vacuuming, gardening, or anything else that causes a small increase in your breathing or heart. The total volume of vigorous (moderate) activity in a week was calculated by summing responses to each of the total vigorous (moderate) activity (frequency*duration) items. For example, a total volume of 90 minutes/week would be derived from summing responses for moderate activity of three days of moderate activity at 20 minutes/day for 60 total minutes and vigorous activity for two days/week at 15 min/day.

Self-management competency score. A summary variable representing three important self-management behaviors was designed by combining individual scores of reported responses regarding self-monitored blood glucose testing (0 = SMBG testing less than daily and 1 = SMBG testing more than once daily), daily aspirin use (0 = no aspirin use and 1 = aspirin use), and tobacco use (0 = tobacco use and 1 = no tobacco use). Reverse coding was used with tobacco use, as zero had originally indicated no smoking and one indicated smoking. If the competency score total was equal to two or greater, it was coded a one for self-management competency. If the score was less than two, it was coded zero or less self-management competency. This competency score was used as a measure of self-management action (greater than or equal to two was determined to measure competency in self-management).

Self-monitored blood glucose (SMBG) testing. The frequency of self-monitored blood glucose testing was measured using self-report of one question based on frequency of testing daily (Harris et al., 2000).

Tobacco use (self-report questionnaire). A survey question from the Alcohol Use Disorders Identification Test (Audit-C) was used to assess tobacco use (Babor et al., 2006). The AUDIT-C is scored on a scale of 0–5 for the question. Points allotted are a = 0 points; b = 1 point; c = 2 points; d = 3 points; e = 4 points.

Aspirin use (self-report questionnaire). Aspirin use by participants was assessed with a baseline survey question: “Do you take aspirin every day?”

A1C–clinical outcomes measure. A clinical measure of self-management included A1c as the primary outcome variable. A1c values and dates for all study-enrolled subjects were collected through passive surveillance of the electronic medical record. A1c tests were done at one of two accredited laboratories using standard high pressure liquid chromatography assay methods with a coefficient of variation (CV) of 1.14% at A1c of 7.5% (HPMG) and a CV of 0.82% at an A1c of 6.2% (LCF Research/ABQ HP) (Sperl-Hillen et al., 2013). All A1c data were collected and retained for subjects for six months before the baseline randomization date and for 12.8 months post-randomization.

Demographic, socioeconomic, and clinical intensity characteristics.

Baseline patient characteristics were collected and assessed in the self-report survey designed to develop a more comprehensive profile of the patients and the impact of psychosocial factors on self-management. It was theorized that all demographic,

socioeconomic, and clinical characteristics directly influenced affect, knowledge, and diabetes social support and thus indirectly influenced self-efficacy and self-management behaviors. Age and gender were treated as individual demographic variables in the model. Baseline marital status was utilized to measure functional social support (FSS). The individual's baseline socioeconomic status (SES) factors and clinical intensity variables were used to measure socioeconomic status (SES) and clinical intensity (CI). These measures are discussed in more detail below.

Patient Demographics. The baseline demographic covariates of age (continuous) and gender (categorical) were tested independently for their direct impact on the psychosocial variables.

Patient Socioeconomic Status (SES) Measures. Due to their potential direct impact on the mediating and outcome variables, the baseline patient socioeconomic status (SES) variables measured were collected at baseline (T0). The SES measures collected included education, household income, and employment status and were modeled as exogenous observed variables.

Clinical Intensity Measures. The initial model identified two clinical variables intended to provide a measure for clinical intensity (CI). These clinical intensity measures initially included duration of disease (continuous) and insulin use (binomial). After principal factor analysis during the measurement model step, it was determined that the clinical intensity measures were separate factors, and thus they were not used as a latent measure of clinical intensity. The two factors were modeled as exogenous observed variables.

Duration of Disease. The length of time a patient had been diagnosed with diabetes, also known as the duration of disease, was obtained as self-report data at the first visit for baseline screening and validated against the patient's electronic medical record when possible.

Insulin Use. The information regarding insulin use was determined using six months of prior pharmacy claims data at baseline, and two follow-up time points at six months after randomization (short-term follow-up) and 12 months after randomization (long-term follow up) (Sperl-Hillen et al., 2011). Medication data were obtained through surveillance of medical claims on the subset of subjects (n=488, 78%) with health plan pharmacy coverage through the research delivery organizations. A patient was defined as “using” a drug class if they had any claim for a drug in that class in the prior six months (Sperl-Hillen et al., 2011).

Methods: Approach to Statistical Analysis

Statistical Software. All statistical analyses were conducted using SAS versions 9.2 and 9.3 software, and SAS Structural Equation Modeling was conducted using JMP Professional 10.0.1, 10.0.2 and 11.0 (Cary, 2011). The estimation for the confirmatory factor analysis was done both using principal components analysis within JMP 11.0. The estimation method for the structural equation modeling used PROC CALIS to test the measurement model and the structural model using full maximum likelihood estimation for raw data analyses and maximum likelihood estimation for covariance data analyses.

Background on Structural Equation Modeling. In experimental research, structural equation modeling (SEM) is a statistical technique for modeling hypothesized relationships among variables using covariance data. It allows researchers the ability to examine the plausibility of their notions about relationships and directional influence (Pearl & Hoyle, 2011). Structural equation modeling (SEM) was used to evaluate the complex multivariate hypotheses, as it allows the entire conceptual model to be specified and tested to determine the degree to which the hypothesized model is consistent with the data (Byrne, 2006). SEM is most valuable for studies that hypothesize mediation by variables that transmit the effects of the manipulations (Maruyama, 1998; Klein, 2011). SEM allows for the specification and modeling of more complex paths (i.e., direct and indirect effects) between variables that can be tested within the theoretical model (Maddigan et al., 2005; Pearl & Hoyle, 2011).

The use of SEM allows for the inclusion of both observed and unobserved (latent) variables into theoretically based probability models. It determines if latent constructs, or variables that are not measured, are probable constructs using data from observed variables. SEM is able to incorporate latent variables with multiple indicators (i.e., affect, social support), whereas regression analysis does not allow for the inclusion of multiple indicators (Byrne, 2006; Bollen & Curran, 2006). SEM is a generalization of multiple regressions that allows testing of causal assumptions (Bollen & Curran, 2006; Pearl & Hoyle, 2011).

Theory is the centerpiece for SEM (Maruyama, 1998). SEM methods start with a conceptual model that specifies the relationships among a set of variables. Reality dictates that cause and effect exist independently of our ideas about how they work. In models, cause and effect are very dependent on the way in which the relationships are specified, and results from SEM speak to the “plausibility” of the specified model (Maruyama, 1998; Pearl & Hoyle, 2011).

SEM is useful in research situations where the researcher wants to know not only how well the predictors explain the criterion variable but also which specific predictors are most important in the findings (Maruyama, 1998). SEM has shown utility in studying complex systems, including its capacity and flexibility as a statistical modeling framework. In advancing a patient-centered integration of social sciences and clinical sciences theory and empirical evidence and the need to study multiple causes simultaneously, SEM has become of more interest (Bollen & Curran, 2006; Pearl & Hoyle, 2011).

The next chapter will describe the descriptive data analysis and the five steps of the SEM methodology used to obtain the results and test the hypotheses (Klein, 2011). The SEM phases used to obtain and evaluate the results of the study include 1) theoretical model specification, as shared previously in this chapter; 2) model identification, or determining whether is it possible to derive a unique set of model parameter estimates; 3) selection of measurement and data collection as discussed in this chapter; 4) estimation of both the confirmatory factors analyses and the structural equation modeling; and 5) model respecification as needed.

Chapter 4 - Results of the Study

This chapter reviews the results from the statistical analysis, including the descriptive statistics, correlations, measurement and structural equation modeling analyses, as well as the hypothesis testing.

Descriptive Analysis of Data

Follow-up survey return rates ranged from 82–90% between six months and twelve months. The classified socioeconomic (demographic and lifestyle) factors were set up categorically. The psychosocial measures were primarily categorical (ordinal) variables. Psychosocial scores were standardized by dividing each individual's baseline score by the standard deviation of the treatment group's scores (i.e., the measures were rescaled) to allow effect sizes to be compared across the different measures. Age, A1c, BMI, and duration of diabetes were continuous variables.

A preliminary analysis of the data involved reviewing descriptive statistic means, standard deviations, observed ranges, correlations, and skewness and kurtosis of the variables for time periods T0 (baseline) and T4 (twelve months).

Multi-normality analysis of data. In structural models, as opposed to functional models, all variables are taken to be random rather than having fixed levels. For maximum likelihood estimation in PROC CALIS, the random variables are assumed to have an approximately multivariate normal distribution. Non-normality, especially high kurtosis, can produce poor estimates and grossly incorrect standard errors and hypothesis tests, even in large samples. The

assumption of normality is more important in SEM than in models with nonstochastic exogenous variables (www.SAS.com, 2011). The use of maximum likelihood (ML) allows for non-normal data to be analyzed with an estimation method that assumes normality (SEM), provided test statistics are calculated that correct for non-normality (Klein, 2011).

In order to evaluate the assumption of multivariate normality, the data was screened by reviewing the univariate distributions of all variables using correlation and covariance matrices, skewness and kurtosis, and checking for collinearity where possible. The skewness and kurtosis of the seventy variables were reviewed for extreme measures. The ratio of the value of either the skew index (SI) or kurtosis index (KI) over its standard error is interpreted as a z-test of the null hypothesis, that there is no population skew or kurtosis (Klein, 2011). Some variables did show positive or negative skew in the initial distribution analysis, but all variables were within the acceptable range value of the SI ($SI > 3$ = extremely skewed) and KI ($KI > 8$) recommended indexes; thus, the assumption of multivariate normality was possible (Klein, 2011). After model analysis, the PHQ-9 results was the only variable that was logarithmically transformed (\log_{10}) to address slight positive skew.

The covariances and eigenvalues for all study factors were reviewed, and the subsequent data matrices were shown to be positive definite by using an outside program from the SAS Institute, as PROC CALIS does not actually calculate these in its programming. To be positive definite (PD), the matrix must have the

following characteristics: a) matrix is nonsingular; b) all eigenvalues are positive (>0); c) the determinant (eigenvalue) of a positive definite matrix is greater than zero; and d) in the PD matrix, none of the correlations or covariances are out of bounds or mathematically impossible to derive (Klein, 2011).

Scaling was required prior to using the covariance data matrix table for PROC CALIS SEM estimation. The rule of scaling is required for variables to ensure they did not vary larger than 1 to 10 (Klein, 2011). The variables rescaled included PAID (/100), health literacy (/100), rfs (/10), age (/100), and duration of diabetes (/10). The A1c variable was reversed as a lower A1c is more positive and all other scales in the self-management factor were positive as they increased.

Descriptive data. Of the 564 subjects under study, 317 (56.2%) were associated with HealthPartners Research Foundation (HP) in Minneapolis, Minnesota, and 247 (43.8%) were associated with Lovelace Clinic Foundation (LCF) in Albuquerque, New Mexico. The mean age was 62.4 years, and 50% were women. Sixty-six percent were white, with 34% non-white (22% Hispanic, 6% Black, and 6% other race/ethnicity). Educational status was relatively high (77% with some college up to college graduate plus and 23% with high school or less than high school), 37% were working, and 15% had an income of less than \$20,000. Mean duration of diabetes was 11.77 years, and the baseline (TO) BMI study mean was 34.4, compared to a mean of 34.1 at T4. Seventy percent of patients were not using insulin at baseline compared to 30% who were using insulin. Table 5 describes the baseline-controlling characteristics of IDEA study subjects.

The diabetes empowerment score (DES scale 0-5) was a mean of $3.80 \pm .53$ at baseline and a mean of 3.89 at T4. The PAID score was a mean of $29.99 \pm .21$.06 and health literacy was high at a mean of 56.5 out of range of 39–60. The PHQ-2 had a mean of 1.90 ± 1.09 and the PHQ-9 had a mean of 5.64 ± 5.27 . Baseline A1c (T0) was a mean of 8.14 ± 1.43 and ranged from 7.0 to 15.40. A1c dropped significantly in the twelve-month follow-up period to a mean of 7.79 (T4) ranging from 4.9 to 14.4 or a 5% reduction overall (Sperl-Hillen et al., 2013) (See Table 5).

Table 5

Main Participant Measures at Baseline. (Includes descriptive statistics for 564 participants who completed data but were not 100% complete at T0 & T4)

Characteristics	T0 (Baseline) 564	Percent (%) or SD (\pm)
N (study participants)	564	
Site distribution		
HP/HPMG	317	56.2%
LCF/ABQ	247	43.8%
Age (years)	62.35	\pm 11.12
Sex (women)	281	49.8%
Race/Ethnicity		
White	372	66%
Black/Hispanic/Other	189	34%
Education		
<High school & HS grad	129	23.1%
Some college & \geq college grad+	432	76.9%
Income		
<\$20,000	79	15%
\$20K-\$70,000+	433	85%
Employment		
Working	209	37%
Retired/disabled/other	354	63%
Marital Status ^b		
Married	367	66%
Not married/widowed/separated	193	34%
No. of additional people in household Mean \pm SD	1.377	\pm 1.20
Duration of diabetes, mean \pm SD, years	11.77	\pm 8.254
BMI, mean \pm SD, kg/m ²	34.44	\pm 7.57
Baseline insulin dependent (1) (0)	171 393	30% 70%
Baseline A1c Mean of A1C + (SD)	8.135	\pm 1.43

The initial randomization of subjects into three treatment groups resulted in balanced group characteristics for enrolled subjects with a mean age of 62, 49% women, 22% high school graduate or less, and 64% married. Imbalance across treatment groups was noted for mean (SD) duration of diabetes of 11.9 (+8.2) for individual education (IE), 10.7 (+6.9) for group education (GP), and 13 (+.22) for usual care (UC), $p=.04$; and numbers of subjects using insulin, IE = 63 (32.5%), GE=42 (22.7%), UC = 40 (36.7%), $p=.02$ (Sperl-Hillen et al., 2013).

Structural Equation Modeling Methods Approach

The a priori conceptual model was developed using a review of previous studies (DePalma et al., 2011; Nozaki, 2009; Williams et al., 2004, 2008; Nakahara et al., 2006). Sample SEM equations used to evaluate the model are reviewed. The estimation of the model utilized a five-step SEM method described in more detail below, including 1) conceptual model specification; 2) model identification; 3) measurement specification; 4) estimation of both measurement model and structural model; and 5) model respecification, as required (Klein, 2011). A correlation analysis was conducted and evaluated as an important step in the SEM measurement process. In step 4, a two-step measurement and structural equation modeling estimation procedure was used to assess the potential direct and indirect relationships between the psychosocial factors, self-efficacy, and self-management behaviors and the A1c outcome. Following the model respecification, the results section of the final respecified models are shown in detailed tables and figures and in Appendix B.

Equations. In this structural equation model, the exogenous variables are labeled χ_i , for person i , including the sociodemographic variables and dummy variables for age, gender, ethnicity, education level, employment status, duration of diabetes, insulin use, and marital status (χ_i). The vector of the four latent variables is signified by Γ . Thus, the model is as follows: $\eta_i = \eta_i\beta + \chi_i' \Gamma + \zeta_i$, where β is a matrix of parameters with nonzero elements corresponding to the arrows in the conceptual model to capture the influence of these latent variables (Γ) on each other, and Γ is a matrix of parameters capturing the influence of the exogenous variables on ζ_i . The error vector (ζ_i) is assumed to be independent with free variance parameters, as correlations are captured in the matrix B . Note that the exogenous variables in χ_i influence the value of a particular g_{ij} , both directly and through their influence on the other values in g_i . The observed outcomes resulting from these latent variables are labeled Y_i and represent their relationship to g_i through the following sample equations:

$$X_1 = \lambda_{11}\xi_1 + \lambda_{12}\xi_2 + \delta_1$$

$$X_2 = \lambda_{21}\xi_1 + \lambda_{22}\xi_2 + \delta_2$$

where λ is a block-diagonal matrix, with each block a column of parameters capturing the relationships between the latent variable and the multiple measures of that latent concept. The value of λ in each equation is fixed to one, to scale or normalize the level of the estimated latent variables (Carlin, Christianson, Keenan, & Finch, 2012).

The SEM code used illustrates the PROC CALIS pathways that were used in the hypothesis testing between the exogenous, endogenous, and outcome variables (see Appendix C).

Step 1: Specification of the conceptual model.

The specification of the proposed conceptual model and its hypotheses built upon theory is the first step in structural equation modeling. Chapters 1–3 were used to describe the theory for the direction and placement of each indicator and latent factor proposed within the model. The figure below represents the conceptual model including on the left side, the exogenous demographic, SES, clinical intensity and marital status characteristics of the participants in the study. As the factors not explained directly by the proposed conceptual model, or exogenous factors, they are included because of known associations from the literature.

Next in the proposed conceptual model itself, the second section on the left represents the proposed modeling for each latent factor (oval) for diabetes social support, knowledge, affect, and self-efficacy. Self-efficacy serves as both a dependent variable (Y) of the other psychosocial factors of affect, knowledge and diabetes social support directly and an independent variable (X) in the analysis of SE as a mediator between the psychosocial factors (X) and self-management behaviors (Y). The dependent variables of self-management behaviors including A1c outcomes are each studied separately and are represented as separate observed indicators (Y1-Y5) (see Figure 5). Model symbolism is identified and specification of the model is reviewed in more detail below.

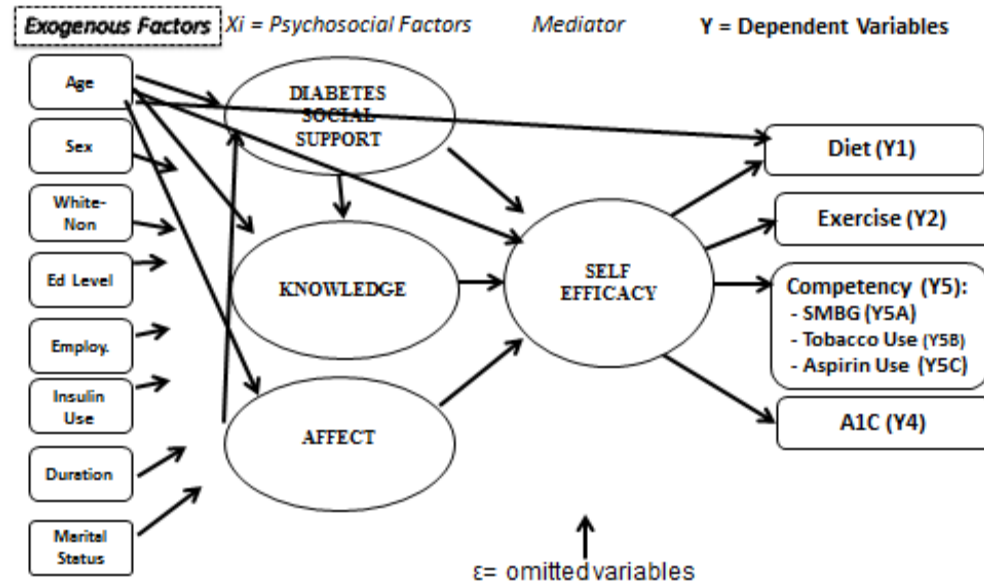



Figure 5. Proposed a priori conceptual model depicting the exogenous characteristics and the endogenous latent factors with their indicators under study.

The model diagram uses symbolism from the McArdle-McDonald reticular action model (RAM), where every model parameter is explicitly displayed using the following symbols and is aligned with the previously stated hypotheses:

- Latent variables are represented using ellipses (i.e., ).
- \rightarrow represents the direct effect or path coefficients (B 's) and the direction hypothesized between latent factors.
- The dependent variables (self-management behaviors and A1c were each studied separately against the full model and thus represented using individual indicator boxes)

The conceptual structural model proposes hypotheses about effect priority and can be read from left to right as it is proposing that X (psychosocial factors) are causing Y (self-management behaviors and A1c scores). Exogenous characteristics on the far left recognize the need to account for the impact of demographic, SES and clinical intensity factors on self-efficacy and self-management. The model proposes that affect, knowledge, and diabetes social support (DSS) directly influence self-efficacy. In addition, the model shows the hypothesis that affect is directly influencing DSS and that DSS directly influences knowledge. SE serves as both a predictor and a criterion, mediating the three psychosocial factors and directly influencing self-management behaviors and A1c levels. This model proposes that there are no significant direct influences between DSS, knowledge, and affect to self-management behaviors, only indirectly through SE.

Statistical estimates of direct effects are path coefficients (β 's) and similar to regression coefficients (Klein, 2011). The model presumed directional effects are detailed in the hypotheses outlined in Chapter 1 and further examined in the results section in Chapter 4. For example, it was hypothesized that as affect increases (increasing distress and depression), diabetes social support would decrease and self-efficacy would decrease, and thus self-management behaviors would decrease as well.

The multiple-indicator measurement approach describes the primary indicator variables (observed) studied due to their potential influence on the phenomena of self-efficacy and self-management. Each latent factor was comprised

of two or more observed measures in an effort to develop a more robust latent measure. The measurement constructs are shown in more detail in the figure below, followed by an explanation of the symbolism of the detailed model (observed indicators, exogenous and endogenous) that includes the measurement indicators making up the constructs of the latent factors (See Figure 6).

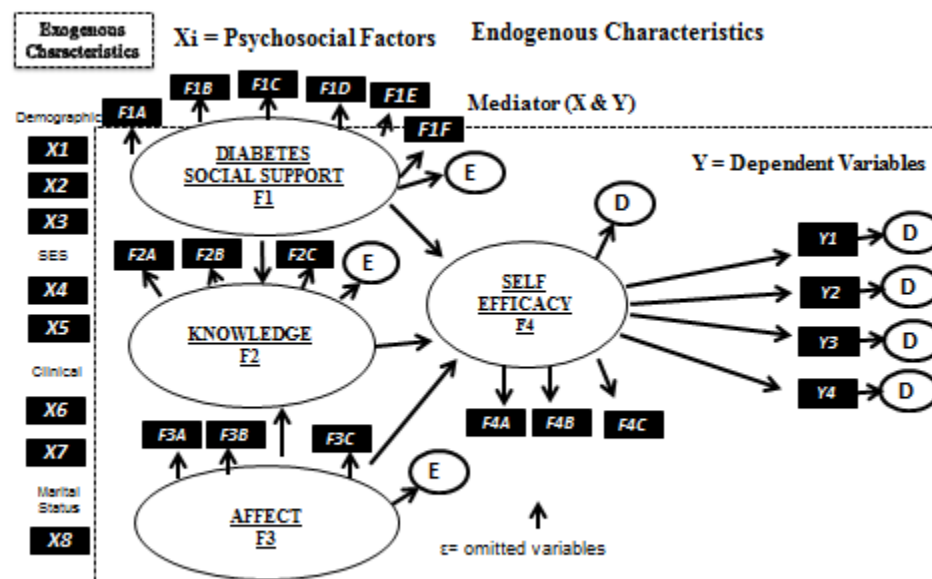



Figure 6. Full model representing the observed indicators (in boxes), latent factors in ovals and dependent (Y) self-management constructs in boxes. Exogenous characteristics on the far left represent demographic, SES, clinical intensity, and marital status. The large box to the right represents the a priori conce

The exogenous characteristics, demographic, SES, clinical and marital status included in the study are noted on the left column (indicators X1-X8). The indicators after model trimming included age, gender, ethnicity, educational status, income, insulin use, duration of diabetes, and marital status. These measures were

included in the model by connecting them to each latent variable in the model to account for the influence they have.

The a priori conceptual model is highlighted in the large box to the right of the exogenous characteristics. Model symbolism is described in more detail below.

- The observed variables for each latent factor are displayed using rectangles (i.e., ).
- Hypothesized directional effects of one variable on another (direct effects/path coefficients) are shown by a line with a single arrowhead (i.e., \rightarrow). The lines with single arrowheads that point from a factor to an indicator, such as $F4 \rightarrow F4A$, represent the presumed effect of the factor on the observed scores. In CFA, parameter estimate interpretation (β 's), factor loadings, estimate the direct effects of factors on indicators and are interpreted as regression coefficients. In the structural equation models, the parameter estimate (β 's) includes direct effects on endogenous variables from other variables, either exogenous or endogenous, and the variances and covariances of exogenous variables.
- The \rightarrow from D to Y (for endogenous factors) or E to X (for exogenous variables) represents the residuals or unexplained variance of all unmeasured causes on Y including measurement error. The D (or E) itself can also be considered an unmeasured (latent) exogenous variable.
- The outcome or dependent variables (Y's) are represented in the model as endogenous variables (self-efficacy and self-management). The presumed

causes of the variables are modeled by other factors (diabetes social support, knowledge, and affect for SE and self-efficacy for self-management).

- The numeral (1) that appears in the diagram next to a path from the factor to one of the indicators represents a scaling constant for identification, which is required for the statistical program to estimate factor variances and covariances.
- Covariances (unstandardized solution) or correlations (standardized solution) between independent variables are displayed using a curved line with two arrowheads (Ω). This symbol represents that the variance of an exogenous variable is free to both vary and covary and connects every observed or latent exogenous variable to itself (Klein, 2011). This symbol also describes an unanalyzed association between two exogenous variables (meaning the value is there but it is not a prediction or hypothesized variable).

As the model does not represent all factors influencing self-management, omitted variables are noted at the bottom of the model. Omitted variables, such as patient-provider interaction, are known influences on self-efficacy and self-management, but were not included in this modeling. The possibility of the specification error of omitting causal variables in SEM is similar to regression (Klein, 2011).

The detailed variables table below summarizes the study's baseline demographic, socioeconomic status, and clinical intensity covariates, the IDEA

study observed psychosocial measures fit to each latent construct, method(s) of data collection, type of variable, and the time period within the study when the data was collected (see Table 6). The numbers on the factors and indicators in the table correspond to those noted in Figure 6 above.

Table 6

Observed Study Measures Used in the Proposed Conceptual Model

FACTORS AND INDICATOR VARIABLES	IDEA SURVEY INSTRUMENT EHR = Electronic Health Record SRS= Self-Report Survey OEV = Original Enrollment Visit	TYPE OF VARIABLE Continuous Categorical Nominal	TIMING: T₀ = Baseline T₄ = 12 months
STUDY_SITE	IDEA Study Records	Nominal (0 = Albq, 1= HP)	T ₀
Randomized Education Intervention	IDEA Study Records	Categorical Ordinal	T ₀ & T ₄
Demographics			
Age (X1)	EHR & SRS	Continuous	T ₀
Gender (X2)	EHR & SRS =	Dichotomous (Nominal)	T ₀
Race/Ethnicity (White_non_cat) = (X3)	EHR & SRS	Categorical/Nominal	T ₀
Socioeconomic Status			
Educational Level (X4)	SRS	Categorical Nominal	T ₀
Household Income (Trimmed)	SRS	Categorical Ordinal	T ₀
Employment Status (X5)	SRS	Categorical Ordinal	T ₀
Functional Social Support			
Marital Status (X8)	SRS	Nominal Binary	T ₀
No of Additional People in HH (Trimmed)	SRS	Continuous	T ₀
Baseline Clinical Intensity			
Duration of Diabetes (X6)	EHR and SRS	Continuous	T ₀
BMI (Trimmed)	EHR	Continuous	T ₀

Insulin Use (X7)	EHR	Categorical Ordinal	T ₀
DIABETES SOCIAL SUPPORT (F1)			
Social Support Needs Met- meals (F1A)	Survey – DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
Social Support Needs Met- meds (F1B)	Survey –DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
Social Support Needs Met- feet (F1C)	Survey –DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
Social Support Needs Met- exercise (F1D)	Survey – DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
Social Support Needs Met- SMBG (F1E)	Survey –DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
Social Support Needs Met- feelings (F1F)	Survey –DCP (q26a-f)	Categorical Nominal	T ₀ & T ₄
KNOWLEDGE (F2)			
Understanding of Disease (F2A)	Survey –DCP (q 25a-j)	Categorical Ordinal	T ₀ & T ₄
Importance of Care Ability (F2B)	Survey – DCP	Categorical Ordinal	T ₀ & T ₄
Health Literacy (F2C)	LAD	Categorical Ordinal	T ₀
AFFECT (F3)			
Diabetes Distress Scale (F3A)	PAID (Problem Areas in Diabetes Scale) Survey	Categorical Ordinal	T ₀ & T ₄
Attitudes (F3B) Overall	Survey –DCP	Categorical Ordinal	T ₀ & T ₄
Depression (F3C)	Survey – PHQ-9 Module	Categorical Ordinal	T ₀
Depression (F3C)	PHQ-2 Module	Categorical Ordinal	T ₀ & T ₄
SELF EFFICACY (F4)	MEDIATOR		
Self-efficacy in Patients with Diabetes (F4A)	Survey –Diabetes Empowerment Scale (DES-SF)	Categorical Ordinal	T ₀ & T ₄
Care Ability (F4B)	Survey – DCP	Categorical Ordinal	T ₀ & T ₄
Self-Care Ability (F4C)	Survey -DCP - Q189	Categorical Ordinal	T ₀
SELF-MANAGEMENT BEHAVIORS (Y)			
Food Intake (Y1)	Survey - RFS	Continuous	T ₀ & T ₄
Physical Activity (Y2)	Survey -BRFSS	Categorical	T ₀ & T ₄
Glucose Control – A1c (Y3)	HbA1c Levels EHR (53)	Continuous	T ₀ & T ₄
Compliance Score for 3 self-management behaviors (Y4)	Measured by taking 0-1 of SMBG, 0-1 of Aspirin and 0-1	Binary (Yes = 1 (>=2) and 0 = No)If scored less	T ₀ & T ₄

	of Tobacco Use	than 2 = 0 1 = 2 or >	
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Directionality. Since this is modeling concurrent data for T₀, it is difficult to presume causal effects using the above criterion. Use of equivalent models was required for review of the association and reverse association of the major indicator variables. Based on the literature, there is strong theoretical evidence for the proposed direction of self-efficacy impacting self-management. There are various studies showing different causal approaches or directionality with the other psychosocial factors of diabetes social support, knowledge, and affect. This was discussed in more detail in the literature review of the theory in previous chapters. The current model does have sufficient grounding in theory to be plausible.

Model Complexity. The model complexity needed was evaluated during the specification step. The total number of parameters that can be estimated is limited by the number of observations available for the analysis (Klein, 2011). The parameters of structural equation models (β 's) include (1) direct effects on endogenous variables from other variables, either exogenous or endogenous and (2) the variances and covariances of exogenous variables (Rule 5.1, Klein, 2011). Observations in this case do not mean the sample size, but refer to the number of entries in the sample covariance matrix. The number of observations is calculated by Klein's Rule 5.2: "If v is the number of observed variables, then the number of observations equals $v(v+1)/2$ when means are not analyzed" (Klein, 2011). In the analyzed structural models, the number of parameters ranged from 113–118 and observed variables ranged from 24–25 for T₀ and are noted below in Table 7. The

difference between the number of observations and the number of its parameters is the model degrees of freedom or $df_M = p - q$, where p = observations noted above and q = the number of estimated parameters.

For example, in the final respecified model for A1c with lines to self-management, there were 25 variables in the model, 117 parameters, thus $(25*26)/2 = 325$ as number of observations. The model degrees of freedom for this model are calculated using $df_M = p - q$ and are $325 - 117 = 208$. Thus, there are 208 model degrees of freedom.

Table 7

Number of Parameters and Observations to Determine the Model Degrees of Freedom for Model Specification for T0 A1c and T4 A1c.

TIME PERIOD	# of Parameters = q (Rule 5.1)	# of Observations = p (Rule 5.2 $v(v+1)/2$)	Model Degrees of Freedom $df_M = p - q$
T0 A1c (Baseline)	117	325 (25 vars)	$325 - 117 = 208$
T4 A1c (Twelve Months)	103	300 (24 vars)	$300 - 103 = 197$

Type of structural model. The types of structural models are typically recursive or nonrecursive. The assumption of a recursive model includes that all causal effects are unidirectional and that the disturbances are independent. The proposed conceptual model is a partially recursive model, as it has the two basic features of uncorrelated disturbances and unidirectionality of all causal effects. Having two of the independent variables also covary, affect to knowledge and diabetes social support to affect, explains the rationale for the definition of a

partially recursive model. Partially recursive models may be analyzed like recursive models and recursive structural models are identified (Klein, 2011).

Step 2: Model identification.

All structural models, to be estimable, need to be identified (Klein, 2011). It is theoretically possible for the computer to find a unique estimate for every model parameter, if it is identified (Klein, 2011). The identification relates to the model, not the data, so is required regardless of the sample size (Klein, 2011). A quantity Q (M) is identifiable, given a set of assumptions (A), if for any two models $M1$ and $M2$ that satisfy $P(M1) = P(M2) \rightarrow Q(M1) = Q(M2)$. The assumptions in A would constrain the variability of $M1$ and $M2$ in such a way that equality of P 's would entail equality of Q 's. If this happens, Q depends on P only, and should therefore be expressible in terms of the parameters of P (Pearl, 2011).

This structural regression model met the requirements that are first necessary, but not sufficient, for identification including

1. The model degrees of freedom must be at least zero ($df_M \geq 0$).
2. Every latent variable (including the residual terms) must be assigned a scale (metric) (Klein, 2011).

Once the measurement model was determined to be identified, then the structural portion of the SR model must be identified (Klein, 2011). A two-step rule to determine structural model identification was proposed by Bollen (1989), which states that both of the following criteria must be met:

- The measurement part of the model respecified as a CFA model is identified (the measurement model must be identified).
- The structural part of the model is identified (evaluate the structural model against Rules 6.1-6.3) (Klein, 2011).

Finally, because it is a partially recursive path model as noted above (all variables point in one direction), it is identified per Rule 6.1 (Klein, 2011). Another heuristic for models with multiple constructs is the two-indicator rule (Rule 6.5), which states that if a standard model has ≥ 2 indicators per factor, the model is identified (Klein, 2011). Both the proposed measurement and structural model meet the above 6.1–6.5 heuristic rules.

After a further review of observations and parameters, the model was determined to be an overidentified partially recursive model. In structural regression models, the degrees of freedom (df) will be determined by the formula $v(v+1)/2$, where v is the number of measures (Maruyama, 1998). As noted above in model complexity, the degrees of freedom are 208 in T0 and 197 in T4, with multiple variable measures and outcome measures (Y1 – Y5). This is an overidentified structural equation model and is, therefore, identified. An overidentified structural equation model has fewer free parameters than observations ($df_M \geq 0$). The measurement and structural portions of the proposed conceptual model meet the criteria for identification.

Step 3: Measurement selection and data preparation.

The measurement instrument selection and survey methods from the IDEA study were discussed thoroughly in Chapter 3. The IDEA study recruited 623 participants. During the twelve-month period of the study, 15 participants died and one withdrew, leaving a total of 607 patients. When those who had not completed surveys from either T2 or T4 were dropped, 564 (93%) patients remained in the sample for this study. Of the remaining, 225 participants had 100% complete data across both time periods (See Table 8). Multiple variables were collected at baseline (i.e., SES, demographics, and baseline clinical information). Specific self-report and clinical information was collected during both time periods (i.e., psychosocial, BMI, A1c, self-efficacy, and self-management behaviors).

Missing data pattern analysis (T0 and T4). In SEM, missing data is an important part of the analysis, as ML estimation will only include cases with 100% data elements. In analyzing the T0 (Baseline) missing data pattern for the IDEA data, 17 different patterns were identified. Eighty two percent of the participants (463) had no missing data (100% complete) in T0. In addition, the remaining eighteen percent of missing data patterns had a frequency range of 1 to 9 missing columns. There were 27 different patterns in the missing data from T4, with 344, or 61%, of the data 100% complete. The next 32% of data had between 1 and 9 missing columns and the remaining seven percent had between 10 and 23 missing columns.

In analyzing the T0 - T4 data, 69 missing data patterns were found with 280 participants (50%) having 100% complete data. The next 22% or 125 were missing only one column of data. Twenty-three percent had between two and nine missing columns and the remaining seven percent had between 10 and 12 missing columns (see Table 8).

Analyzing the data across time-periods (T0 and T4), 280, or 50%, of cases had 100% complete data. Another 125, or 22%, of participants had only one data item missing. Twenty percent (n=116) of participants were missing 2–4 variables, for a cumulative total of 92% of the patients having four or fewer variable columns missing over the two time periods. Table 8 below summarizes the details of the missing data columns (variables) by the number and their cumulative percent missing by each data period and overall.

The missing data increasing from baseline with panel data is typically noted in longitudinal studies. The missing data in T4 was greater with 344 participants having 100% complete data. The missing data ranges for T4 were higher as there were 36 (9%) participants with over 10 columns with missing data were missing greater than 10%. Overall panel data collection rates were strong across the study time, as both T2 and T4 had 93% of data with less than 10 columns missing and were very similar in response rates (See Table 8).

Table 8

Time Periods T0, T4 and Overall T0 & T4 Missing Data Pattern Analysis by the Number of Columns Missing (Number and Cumulative Percent) and Patterns.

Missing Data Columns (# of columns)/# of patterns	T0 (17 patterns)		T4 (27 patterns)		OVERALL T0 & T4 (69 patterns)	OVERALL T0 & T4
Range	#	Cum %	#	Cum %	#	Cum %
0	463	82%	344	65%	280	50%
1	74	95%	70	87%	125	72%
2 to 4	9	97%	83	93%	116	92%
5 to 9	18	100%	29	94%	7	93%
10 to 23	0	100%	38	100%	36	100%
TOTAL	564		564		564	

There is limited missing variables in T0 (baseline), as the majority of data was collected at the enrollment visit in person with 13 (89%) variables having 0-5% missing data, 4 (11%) variables having 6-9% and 0 variables having more than 10% missing data (see Table 9). In T4, zero independent variables had 0-5% missing data and six variables had 5-9.9% missing data. The T4 independent variables with missing data greater than 10% were attitude, PHQ-2, care-ability, and health literacy.

When summing the total of participants with 10 or less variables missing out of 27 total variables, 93% are included (17 in T0 and 10 in T4), The remaining 7% of patients have 10–12 variables missing in T4 with A1c being the variable with the most missing data (See Table 9).

Table 9

Overview of Missing Variables Data by Percentage Range of Data Missing for X & Y Variables

Variables Missing Data by Range	T0 (Baseline)	% of total	T4 (12 Months)	%
	N = 564		N=564	
Type of Variable (Demographic, X or Y)	# of Vars		# of Vars	%
Demographic/SES/ Clinical Intensity =Exogenous Variables	13		3	
X VARS				
0-5 % missing	13	89%	0	0%
6-9.9% missing	4	11%	6	60%
10-16 % missing	0	0%	4	40%
X Vars Missing Data 6-10%			Attitude; PHQ-2; Care- Ability; Health Literacy	
TOTAL	17	100%	10	100%
Y Vars	# of Vars		# of Vars	
0-5%	7	100%	0	0%
6-10%	0	0%	5	83%
10-16%	0	0%	1	17%
TOTAL	7	100%	6	100%
Y Vars Missing Data >10%			A1c –15.4%	

Methods for MAR and arbitrary missing data. Due to the increased computing capability, more sophisticated statistical methods for handling missing data have been developed. The current recommended methods for handling missing data in confirmatory factor analysis and structural equation modeling are direct maximum likelihood (DML) or multiple imputations (MI) (Allison, 2003; Schafer and Graham, 2002). Both approaches use all the available data, that is, N= the total

sample size, including cases with missing data. If MAR is true (and data have a multivariate normal distribution), DML and MI produce parameter estimates, standard errors, and test statistics that are consistent and efficient (Brown, 2006; Graham, 2009). Even though these methods assume multivariate normality, inferences based on direct maximum likelihood can be robust to departures from multivariate normality if the amount of the missing data is not large, because the model is effectively applied not to the entire data set but only to its missing part (Shafer, 1997). When comparing MI (EM) and DML, methodologists generally consider DML the better method in CFA and SEM modeling (Allison, 2003; Graham, 2009). DML is free of the problems associated with using the EM multiple imputation algorithms (Allison, 2003; Graham, 2009).

A review of the missing data patterns at each individual time and overall for the study variables revealed an arbitrary pattern with the continuous variables. The pattern of missing data was determined to be missing at random (MAR). It is impossible to test the condition of MAR in research data because the values of missing data are unknown. Allison states, “In essence, MAR allows missingness to depend on things that are observed, but not on things that are not observed.” (Allison, 2003). The assumption of MAR is possibly met when the probability that the data are missing on Y may depend on the value of X, but it is not related to the value of Y when holding X constant (Brown, 2006). In order to evaluate the MAR assumption, the group means of the missing data were reviewed using the Y variables and X factors.

The choice of which statistical method to use for handling missing data was dependent on the assumed pattern of missingness (MAR), efficiency, consistency, and ease of use. Due to the majority of the variables data having less than 10% missing data, even in T4 study follow-up evaluation period, the data sensitivity analyses were conducted using direct maximum likelihood, also known as Full Information Maximum Likelihood (FIML). FIML uses raw data rather than covariance data and allows for unbiased parameter estimates and maximizing data availability, and so was selected over multiple imputations (Graham, 2009; Klein, 2011; Renner et al., 2012). In order to assess the efficiency of this method for handling missing data compared to the standard maximum likelihood approach using covariance data, two sensitivity analyses were conducted using the 100% T0-T4 complete participants data and using FIML with the raw data of 564 participants. The strength and direction of the results were similar; again indicating the MAR assumption may be valid. These results are reported later in more detail in the sensitivity analysis section.

Step 4: Model estimation (measurement and structural).

The measurement and structural equation models for T0 were estimated using the covariance matrix data generated by the 564 study sample data. As noted previously, scaling of variables was necessary to ensure consistency in the modeling data set.

A series of measurement and structural equation models were evaluated using a recommended two-step procedure in Part A and Part B. Advantages of the

two-step procedure include the generality and flexibility of model specification and the ability to assess fit of the hypothesized model to the observed data (Klein, 2011). Model test statistics were generated and tested how well the fit of the research data was to the proposed conceptual model. Model fit was evaluated by the selected goodness of fit (GOF) test statistic measures and testing for differences using the chi-square difference statistic. The two-step modeling process produced measurement and structural models. Equivalent models were assessed along with conducting two sensitivity analyses to determine the impact of missing data on the estimation model. The following provides an overview of the results from the model estimations completed in this study.

T0 Models 1 & 2 (Part A - CFA measurement model) tested whether each of the psychosocial observed variables were latent constructs (diabetes social support, knowledge, affect and self-efficacy) as hypothesized. Using the chi-square difference test, models 1 (correlated) and 2 (uncorrelated) were evaluated to determine if one or the other was significantly different in matching the study data (see Appendix B).

T0 Model 3 (Part B - structural model - original hypothesized TO A1c model) estimated the original hypothesized model. Based on findings from the measurement and structural estimation steps, the original conceptual model was respecified with approved model trimming and building techniques using the a priori hypotheses. GOF statistics indicated significant difference between the

original model and the respecified model and it was selected and used for Models 4–8.

T0 Models 4 – 7 (Part B - respecified structural models) represents the respecified models for each self-management behavior and A1c. These models were used to evaluate hypotheses 1 and 2, specifically the hypothesized direct and/or indirect effect by diabetes social support, affect, and knowledge on self-efficacy for each self-management behavior and A1c. These same models tested the direct and indirect effects of self-efficacy on each diabetes self-management behavior and A1c. These models were used to determine whether self-efficacy had a mediating effect on self-management behaviors and A1c (see Appendix B).

T0 Models 8A –8C (structural model) estimated hypothesis 3 using the study covariance matrix data modeled separately for each of the three randomized clinical trial groups in the original IDEA Study: usual care, individual education, and group education for T0 and T4. Results of the modeling were used to determine if the educational intervention (or not) showed statistically significant changes in knowledge from T0 to T4.

T0 Models 9–10 (Equivalent Models). To evaluate the final respecified hypothesized model for A1c, it was compared with two equivalent or alternative models (Model 10 and Model 11). These models were theoretically derived nested models in order to challenge the original specified model and then compare the model to determine best model fit.

T0 Models 11 –12 (Sensitivity Analyses). Sensitivity analyses were conducted in Step 4 to explore the robustness of the data and the impact of the method selection for handling of missing data.

Goodness of Fit Measures. Each of the above models was evaluated using test statistic goodness of fit (GOF) measures. There are two broad categories of fit statistics and recommended guidelines for using them. The model test statistics tested whether the covariance matrix implied by the conceptual model is close enough to the sample covariance matrix that the differences might reasonably be due to sampling error (Klein, 2011). The GOF measures were selected based on an analysis of the most commonly reported and accepted indexes within the SEM literature.

The model chi-square test statistic (χ^2) is the most basic test “exact fit” statistic and is the opposite of typical hypothesis rejection, where a significant result indicates “badness of fit.” Normally a nonsignificant chi-square p-value of < 0.05 would be the main GOF index to indicate model fit. Due to a larger sample size for SEM modeling (>300), the chi-square is typically statistically significant. In this research, all χ^2 were statistically significant. Due to the importance of understanding the χ^2 test statistics; the significant results were considered an indication of a potential problem with the model. They were explicitly addressed by reviewing the absolute values of the correlation residuals to determine if any were greater than $>.10$. There were no correlations meeting this level (highly unusual), and thus the

significance of the χ^2 test statistic results were determined to be related to sample size and are reported as a GOF measure in this research.

Another category of GOF model test statistics that provided qualitative information about model fit are approximate and absolute fit indexes. They differ from the chi-square statistic, as they do not determine the limit between where expected levels of chance deviations between the predicted and the sample covariance matrices begin and where evidence of the model begins (Klein, 2011). These statistics provide qualitative descriptive information about model fit (Klein, 2011).

Two of the most widely reported SEM approximate fit statistics are the Steiger-Lind root mean square error of approximation (RMSEA; Steiger, 1990) and the standardized root mean square residual (SRMR; Hu & Bentler, 1989). The RMSEA is a parsimony-corrected index, with an upper and lower 90% confidence interval defined. The RMSEA statistic assumes a noncentral approximate a central chi-square distribution and ranges from zero to one, with smaller values indicating closer fit. It is specifically recommended that values at 0.06 or lower indicate “good fit,” values at 0.08 or lower indicate reasonable fit, and values greater than or equal to 0.10 indicate poor fit (Bollen, 2006). The second GOF approximate fit index, SRMR, scaled as a range of zero to one with zero indicating best fit. SRMR recommended values of 0.05 or lower indicate reasonable fit (Hu and Bentler, 1989). It evaluates the differences between the observed and predicted covariances

and transforms both the sample and predicted covariance matrix into correlation matrices. It measures the mean absolute correlational residual (Klein, 2011).

A third measure, an absolute fit index, commonly reported, is the goodness of fit (GFI) index developed by Joreskog-Sorbom in 1982 (Klein, 2011). This index estimates the proportion of covariances in the sample data matrix explained by the research model. It measures how much better the researcher's model fits compared to no model (Joreskog, 2004). This GFI absolute statistic is acceptable when the GFI is over 0.90 (Bollen, 1989; Bentler, 1980).

The following sections, Part A and Part B, review in detail the results from the two-step measurement and structural model estimation approach. Part A describes the measurement modeling estimation and Part B estimated the structural model from the original hypothesized model and then the respecified model. The hypothesis testing results, equivalent models and the sensitivity analyses results, were evaluated in Part B, structural modeling.

Part A: Measurement modeling-confirmatory factor analysis (CFA).

Confirmatory factor analysis (CFA) is the first in a two-step estimation method for testing structural models in which one or more latent (unobserved) variables are hypothesized to predict (or explain) the correlations among several observed variables (Klein, 2011; Mulaik, 1972). One advantage of SEM is the ability to model theoretically more robust latent (i.e., error-free) constructs from the use of observed (i.e., measured) variables. The CFA of the measurement model

specifies how well the observed variables measure each latent factor and describes the measurement reliability and validity of the measurement instruments.

The measurement error represents two types of unique variance: random error (score unreliability) and all sources of systematic variance not due to the factors $F_i \rightarrow X_iA \leftarrow E_i$. The observed score (X_iA) comprises two components: A true score (T) that represents the construct of interest, and a random error component (E) that is normally distributed with a mean of zero across all cases $X_iA = T_i + E_i$ (Klein, 2011).

The results section below describes the confirmatory factor analysis of the latent measurement factors identified a priori in the proposed conceptual study model in Figure 4 as a key part of its hypotheses. The variable correlations were reviewed prior to moving into CFA measurement modeling. Then the measurement analysis (CFA) of SEM featured a principal components analysis of the latent constructs or factors (latent variables) for diabetes social support, knowledge, affect, and self-efficacy. Both correlated and uncorrelated CFA's measurement models were reviewed and results compared. The CFA approach used multivariate measurement as each factor had multiple indicators loaded on a single factor (at least 2 per factor).

CFA Correlations. Correlation testing of all observed study variables was conducted prior to doing the principal component analyses and CFA procedure analysis. Pairwise correlation of coefficients, using a significance level of 0.05, was conducted to assess the associations between each of the observed study variables

and the hypotheses that the indicator variables measured the proposed latent factors. Most correlations were nonsignificant and ranged from 0.002 to 0.30. Correlations greater than 0.30 and as high as 0.87 were reviewed.

Independent variables. For affect, the indicator correlations of the PAID, PHQ-9, & DCP Attitudes section ranged from .488 to 0.870. The high correlation between the PHQ-2 and PHQ-9 scores ($r=.871$) within the construct of affect shows evidence of convergent validity and is congruent as the PHQ-2 is a subset of two questions from the original nine questions in the PHQ-9. There is high correlation between the PAID score and the attitude section of the DCP ($r=.718$) and between PAID and the PHQ-9 and PHQ-2 at $r=.488$ and $r=.595$ respectively. For knowledge indicators using the DCP sections on understanding and importance of knowledge and health literacy, the range was .005 to .277. Within the six indicators predicting diabetes social support, the correlations of the DCP Social Support sections ranged from 0.355-0.568. The pairwise correlation analysis of the indicator variables specified for the latent variables for diabetes social support, affect, and knowledge are described in more detail in the tables below (see Table 10).

Table 10

Correlations of T0 (Baseline) Psychosocial Indicator Variables for Affect, Knowledge and Diabetes Social Support Study Participants (Those in italics are significant at the $p > .01$ level.)

T0 AFFECT	1	2	3	4
1. t0phq2score	1			
2. t0_phq9scby10	<i>0.871</i>	1		
3. t0_paidscorby100	<i>0.488</i>	<i>0.595</i>	1	
4. t0_att20by10	<i>0.537</i>	<i>0.586</i>	<i>0.718</i>	1

T0 KNOWLEDGE	1	2	3
t0_ump_dcp_score	1		
t0_imp_care_dcp_score	0.216	1	
t0_literacy_by_100	0.156	0.136	1

T0 DIABETES SOCIAL SUPPORT	1	2	3	4	5	6
t0_met_meals	1					
t0_met_meds	0.356	1				
t0_feet_met	0.377	0.569	1			
t0_exercise_met	0.468	0.442	0.453	1		
t0_SMBG_met	0.355	0.542	0.488	0.439	1	
t0_feelings_met	0.389	0.446	0.403	0.491	0.522	1

Dependent variables. The following table highlights the pairwise correlations between the indicator variables of self-efficacy and self-management (see Table 14). Self-efficacy indicators had correlations ranging from 0.428 to 0.736. There is significant correlation between the DES score (Diabetes Empowerment survey instrument) and the DCP section scores from care ability ($r = .482$, $p > \text{value}.001$) and self-care ability ($r = .428$, $p < \text{value}.001$). DCP sections of rating care ability and “do” self-care ability are also significant at $r = .736$ ($p > \text{value}.01$).

A review of the individual self-management behaviors and A1c indicator correlations ranged from 0.028 to 0.263, with significant correlations between A1c and exercise (rec_activ_level) and care ability and self-care ability (see Table 11).

Table 11

T0. (Baseline) Correlations between Items Measuring Constructs for Self-efficacy and Self-management Behaviors

	<u>Factor/Indicator</u>	1	2	3	4	5	6	7
	<u>Self-Efficacy</u>							
1	t0_des_score	1						

2	t0_care_abil_dcp_score	.482*	1					
3	t0_self_care_dcp_score	.428*	.736*	1				
	<u>Self-Management</u>							
4	t0_rfs_sc_10	.093	.103	.127	1			
5	t0_rec_activ_level	.084	.238	.230	.179	1		
6	t0_a1c_rev	.154	.263	.258	.028	.035	1	
7	t0_comp_score	.114	.078	.098	.101	.085	.062	1

Significant correlations at p value <.001 = *

Exogenous variables. The pairwise correlation analysis of the exogenous variables specified for age, gender, ethnicity, SES, clinical intensity variables, and marital status were reviewed. The results indicate congruence with literature overall. The exogenous pairwise correlations are noted in the table below (see Table 12).

Table 12

*Correlations of Exogenous Baseline Variables for Study Participants
(Those with * are significant at the $p > .05$ level)*

	Indicator	1	2	3	4	5	6	7	8
	<u>Demographic</u>								
1	BL_age_by100	1							
2	Gender	.090	1						
3	white_non_cat	.120	.065	1					
	<u>SES</u>								
4	Ed_Level_cat	.094	.071	.165	1				
5	Empstat_cat	.447*	.034	.066	.140	1			
	<u>Clinical Intensity</u>								
6	_dura_by10	.278*	.022	.095	.098	.225	1		
7	t0_insulin_yesno	.017	.029	.104	.036	.012	.344*	1	
	<u>Marital Status</u>								
8	Marital_Status	.100	.250*	.061	.065	.006	.008	.017	1

The correlations between three demographic indicators, age, gender, and ethnicity were not significant. Age was significant with employment status ($r=.447$, $p\text{-value} = .001$), duration of diabetes ($r=.278$, $p\text{-value} = .001$). Insulin dependence

and duration of diabetes were significantly correlated ($r = .344$, $p\text{-value} = .001$).

Two key variables were identified that relate to clinical intensity of the participants, including a significant correlation between duration of diabetes and insulin use ($r=.278$, $p\text{-value} = .001$) and insulin use and duration ($r=.344$, $p\text{-value} = .001$). The correlations are noted in Table 12 and ranged from .006 to 0.447. Marital status and gender were correlated ($r = .250$, $p\text{-value} = .001$).

Part A: CFA - Principal Components Analysis.

The confirmatory factor analysis results section below will review in more detail the findings of the principal components analysis including the eigenvalues and factor loadings estimated. The measurement model analysis was conducted using principal components analysis and SEM CFA analysis to determine if the indicator variables selected represented the latent constructs used in the conceptual model.

Diabetes social support. The diabetes social support latent construct was developed using six original survey questions from two sections from the Social Support portion of the DCP instrument. They used self-report responses from a set of two questions with six items. The first question was “I want a lot of help and support from my family or friends” in six areas: following my meal plan, taking my medicines, taking care of my feet, getting enough physical activity, testing my blood sugar, and handling my feelings about diabetes (support needs). The same six items were included in a second question: “My family and friends help and support me a lot to...” (support received). A new “diabetes social support needs met”

variable was created by taking the difference between social support needs identified and social support needs received to create a new variable called “diabetes social support needs met” for each of the six items in the survey described above. These six indicators were then tested to determine if they could be used to describe a latent factor called “diabetes social support.”

The principal components analysis of the latent factor t0_Diabetes Social Support (F1), implementing principal axis factoring, oblique rotation, and a minimum eigenvalue of one, yielded a one-factor solution explaining 54.2% of the variance in the items. Results showed a one-factor-loading model with an eigenvalue of 3.254, with scores indicating measurement of a uniform concept. The correlations between the six item subscales are noted. The loading matrices were all above .60.

After reviewing the CFA principal components analysis from the initial proposed conceptual model, the functional social support (marital status and number living in household variables) was determined not to measure a latent variable, but two separate indicators. Marital status was moved to the left side of the model to become an exogenous characteristic variable and no longer served as an observed variable for diabetes social support. The number in household variable was later trimmed from the analysis during the model respecification (Step 5) after reviewing the initial CFA results.

Knowledge. The latent factor of “knowledge” (F2) was measured using two sections of the DCP; understanding of disease and importance of care ability, and

health literacy from the LAD. Initially readiness to change was included as a measure of knowledge but was trimmed during respecification. The principal components analysis of the latent factor t0_Knowledge, implementing principal axis factoring, oblique rotation, and a minimum eigenvalue of one, yielded a one-factor solution explaining 44.7% of the variance in the items. Results showed a one-factor-loading model with an eigenvalue of 1.341, with understanding, importance of care ability, and health literacy scores indicating measurement of a uniform concept. The correlations between the three items are available in more detail in Appendix A. A summary of the mean, standard deviations, eigenvalues, and loading matrix for the latent constructs is presented in Table 13. The loading matrices for understanding of care, the importance of care ability, and health literacy were all at or above .60 at .71, .69 and .60, respectively (see Table 13).

Affect. Affect was measured as a latent construct (F3) using self-report measures of depression (PHQ-2 and PHQ-9), distress (PAID), and positive-negative attitudes (DCP) toward diabetes. The principal components analysis of the latent factor t0_Affect, implementing principal axis factoring, oblique rotation, and a minimum eigenvalue of one, yielded a one-factor solution explaining 72.43% of the variance using these items. Results showed a one-factor-loading model with an eigenvalue of 2.89, with the PHQ-2, PHQ-9, PAID, and attitude scores indicating measurement of a uniform concept. The correlation between the four item subscales were .879 (to_PHQ-2 and t0_PHQ-9); .488 between t0_PAID and t0_PHQ-2; .533

between t0_PHQ-2 and t0_attitude. The loading matrices were all above .80, which suggests convergent validity (See Appendix A.)

Table 13

Mean, Standard Deviations, Eigenvalues, Cumulative Percent, Loading Matrix for Psychosocial Factors of Diabetes Social Support, Affect, and Knowledge

MEASUREME NT MODEL LATENT FACTORS	INDICATORS	Mean	SD	Eigen- value	Cum. % Loadi ng	Loadi ng Matri x
DIABETES SOCIAL SUPPORT	T0			3.25		
	Supp_needs_meals	.625	0.48		52.24	0.66
	Supp_needs-meds	.825	0.38		66.8	0.77
	Supp_needs_feet	.787	0.41		77.28	0.75
	Supp_needs_exercise	.649	0.47		85.7	0.75
	Supp_needs_SMBG	.785	0.41		93.05	0.77
	Supp_feelings_met	.704	0.45		100	0.74
AFFECT	T0			2.92		
	rev_t0_phq2_score	4.96	1.38		72.77	0.85
	t0_phq9_rev_10	20.0	5.59		89.88	0.91
	t0_PAID_rev_100	70.5	20.6		96.93	0.82
	t0_attit_rev_by10	3.59	7.36		100	0.83
KNOWLEDGE	T0			1.340		
	t0_ump_dcp_score	3.02	0.79		44.7	0.71
	t0_imp_care_dcp_score	4.46	0.66		73.9	0.69
	t0_literacy_by_100	56.5	3.28		100	0.60

Self-efficacy. Self-efficacy (F4) included self-report measures of diabetes empowerment (self-efficacy) using the diabetes empowerment survey (DES), and care ability and self-management rating of actual ability from the DCP survey. The DES measure was not found to be correlated with age, duration of diabetes, or

education, which makes it usable with different age groups and individuals of various socioeconomic backgrounds. This measure was positively correlated with self-reported self-care activities and negatively correlated with glycemic control (A1c). These correlations support the validity of the measure. The internal consistency of this instrument (Wallston et al., 2007) was found to be valid, with a Cronbach's alpha of .83. In the current sample, the mean score on the scale was 27.36 (SD=6.29, Min. =12, Max. =40). As far as internal consistency, Cronbach's alpha was computed to be .87, indicating acceptable internal consistency of the items of the scale. There were no significant mean-level differences among individuals of different racial/ethnic backgrounds, or between males and females. However, individuals with less education (high school or less) scored significantly lower than the other two groups (i.e., "Some College No Degree" and "College Degree or More"): $F(2,121) = 10.66, p < .001$ (Sperl-Hillen, 2011).

The principal components analysis of the latent factor t0_Self Efficacy, implementing principal axis factoring, oblique rotation, and a minimum eigenvalue of 1, yielded a one-factor solution explaining 70% of the variance in the items. Results showed a one-factor-loading model with an eigenvalue of 2.11, with diabetes empowerment, care ability and self-management ability scores indicating measurement of a uniform concept. The loading matrices were both above 0.60 (see Table 14).

Table 14

Mean, Standard. Deviations, Eigenvalues, Cumulative Percent, Loading Matrix for Self-efficacy and Self-management

LATENT FACTOR	INDICATORS	Mean	SD	Eigenvalue	Cum. % Loading	Loading Matrix
SELF-EFFICACY	T0					
	t0_des_score	3.80	0.53	2.11	70	0.73
	t0_care_ability_dcp_score	2.90	0.87	0.63	91	0.90
	t0_self_care_dcp_score	3.24	0.73	0.26	100	0.88

Correlated and Uncorrelated CFA Analysis. Using SEM modeling for the CFA required building and testing two models, a correlated model and an uncorrelated latent factor model. Using the covariance database, which includes the variances from each variable and covariances for each pair of variables, from the responses to multiple indicator variables selected.

As noted previously, the recommended ratio of sample size to the number of free parameters estimated may go as low as 5:1. In this study, the measurement sampling numbers were achieved at a ratio of 5:1. Consequently, there is confidence in the z scores obtained on the significance of the parameters.

The latent factor, diabetes social support (DSS) (F1), was measured by the six subscales from the two sections of the DCP social support section (F1A-F1F). Knowledge (F2), as a latent factor, was measured by two knowledge sections of the DCP instrument, importance of care and understanding of care, and the health literacy (LAD) tool (F2A-F2C). Affect (F3) as a latent factor was measured using

the PHQ-2 and PHQ-9, DCP attitudes section and PAID instruments (F3A-F3C). Finally, self-efficacy (F4) was measured using two sections from the DCP, care ability and self-care ability, and the DES (F4A-F4C). In the correlated model testing, the latent variables were allowed to covary. Both unstandardized and standardized results are shown in the figures below (See Figures 7 and 8).

The CFA unstandardized results show the factor loadings or estimates of the direct effects of the latent factors on the indicator variables. Each estimated path coefficient is displayed next to the path from one variable to its factor. In the unstandardized solution, the factor loadings that were fixed to 1.0 to scale the corresponding factor are not tested for statistical significance because they have no standard errors (Klein, 2011). The parameter estimates that differ significantly from zero (based on t tests) are marked with asterisks. Two asterisks (**) indicates significance level of $p < 0.01$; one asterisk (*) indicates significance at the $p < 0.05$ level.

In reviewing the correlated unstandardized CFA modeling results, since the unstandardized factor loading is 2.407** for the direct effect F3 (Affect) → X (DCP – attitude), then a 2.407 point difference in indicator X (attitude score) given a difference of 1 point on factor F3 (Affect) is predicted. The factor loading for the direct effect F4 (SE) → X (DCP – self-care ability) is .820**, thus a .820 point difference in indicator X (self-care ability) given a difference of 1 point on factor F4 (SE) is predicted. The other unstandardized factor loadings from the correlated modeling are displayed in Figure 7 below.

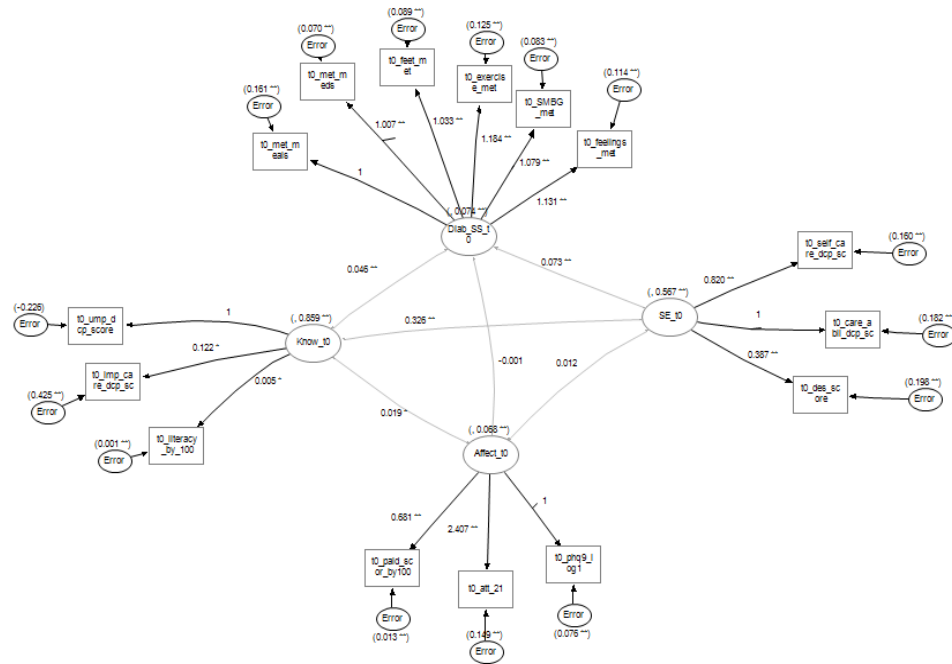


Figure 7. Unstandardized results from correlated CFA analysis of the 564 cov_data. All key latent factors are allowed to covary (fit is significantly better than uncorrelated model).

As the indicators are specified to load on a single factor, the standardized factor loadings are correlations between the indicator and its factor. The squared standardized loadings are proportions of explained variance, or R^2 (Klein, 2011). For example, the standardized loading of dcp_ attitude was .852, the factor (Affect) explains $.852^2 = .726$ or 73% of the variance of the indicator (attitude). Ideally, a

CFA model should explain the majority of the variance ($R^2 > .50$) of each indicator.

Detailed results of the correlated standardized loadings are shown below in Figure 8

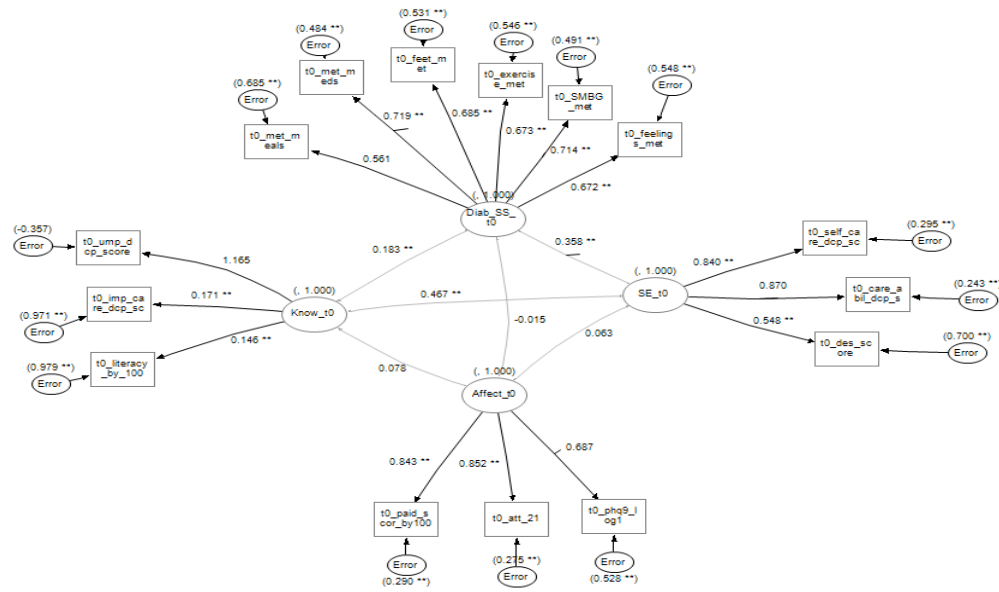


Figure 8. Standardized results from correlated CFA analysis of the 564 cov_data. All key latent factors are allowed to covary (fit is significantly better than uncorrelated model).

In the uncorrelated model testing, the covariance parameters are constrained to zero, so that the latent variables are uncorrelated with each other. Both uncorrelated unstandardized and standardized models were reviewed. The uncorrelated unstandardized model is shown in the figure below and the

standardized model is shown in Appendix B (See Figure 9).

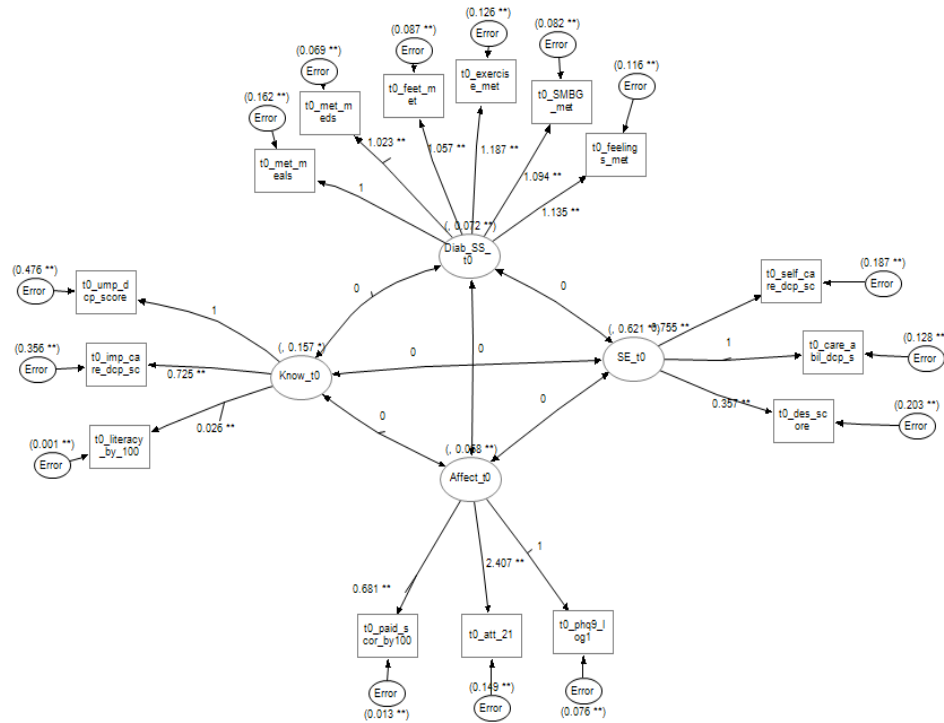


Figure 9. Unstandardized results from uncorrelated CFA analysis of the 564 cov_data. All key latent factors are constrained to zero to disallow covarying (fit is significantly different from the correlated model).

Comparing the models. All models converged properly and the model fit statistic results are noted in Table 15 below. The path to factor parameter results show significance between all factors at the $p < .01$ level and all covariance parameters are significant at the $p < .01$. The factor to factor paths are significant

except between affect and diabetes social support and affect and SE. These results indicate that the paths in this model represent significant relationships among most of the variables except those noted.

Table 15

Goodness of Fit Statistics RMSEA, SRMR, GFI & X², comparison of the correlated and uncorrelated measurement models, 564 T0 data for DSS, Knowledge, Affect and Self-efficacy. Results of chi-square difference test are noted.

Fit Statistics Analysis	# Parameters	# of Variables	RMSEA Estimate (PI)	RMSEA Lower 90% CL	RMSEA Upper 90% CL	Std. RM R (SRMR) (AI)	(GFI) (AI)	X ²	X ² DF	Pr > X ²	X ² Diff if Test	Sign/N S
Measurement Model (n=564)												
CFA CORR A&K & DSS& SE	36	15	.048	.039	.057	.046	.96	191	84	0		
CFA UNCORR A & K & DSS & SE	30	15	.079	.071	.087	.117	.91	407	90	0	6	216
												P value < .001

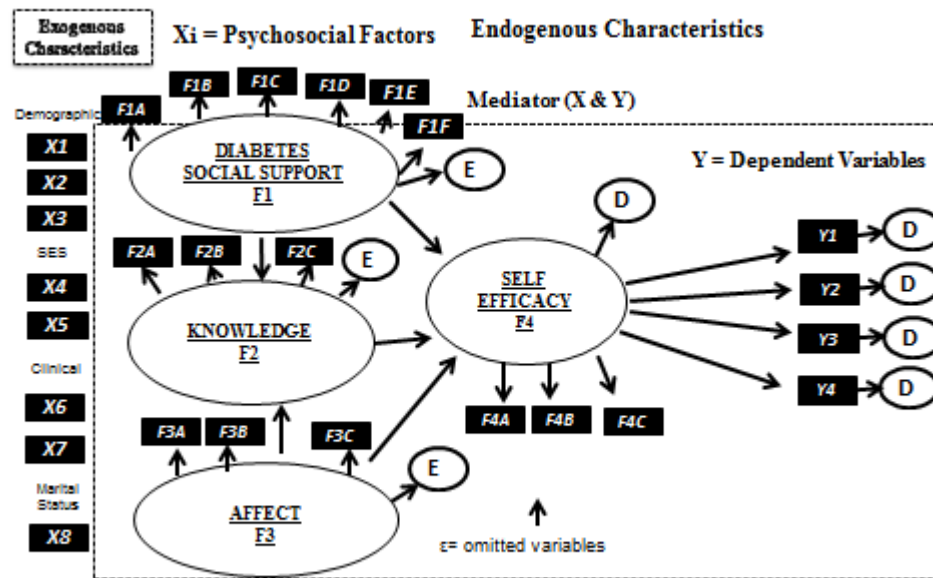
Reviewing the fit statistics for the uncorrelated model, the RMSEA does not meet the acceptable range, as its upper control limit as it is greater than .07. The SRMR test statistic for the uncorrelated model does not fall within the acceptable range, as it is above .05. Using the chi-square difference test, there was a significant difference between the two models (X² difference = 217 with df = 6 and p value < .001). Reviewing the fit statistics above, this chi square difference test indicates that the correlated latent variables model significantly describes a better model for the observed data than the uncorrelated latent variables model.

Part B: Structural equation modeling. SEM was used to specify the direct and indirect relationships among the latent variables (Nakahara, 2006). Hypotheses regarding the specific structural relations of the constructs in the model were evaluated through inspection of the direction and magnitude of the path coefficients. A path coefficient is a standardized regression coefficient (β =beta) showing the direct effect of one variable on another variable. When there are two or more variables, the path coefficients reflect the effect of one variable, controlling for all other variables. Path coefficients are decomposed into direct and indirect effects, corresponding to direct and indirect arrows in a path model. A direct effect occurs when variable X1 is significantly related to variable X2, whereas an indirect effect occurs when variable X3 is related to variable X1 and a part of this relationship is transmitted through variable X2 (i.e., part of that “direct effect” is due to relations between X1 and X3). To test the hypothesis that X has no direct effect on Y corresponds to the specification that the coefficient for the path $X \rightarrow Y$ is fixed to zero (Osborn et al., 2010). It was then tested by specifying that a previously fixed-to-zero parameter becomes a free parameter or vice versa. Results of such analyses may indicate whether to respecify a model by making it more complex (an effect is added—a fixed parameter becomes a free parameter) or more parsimonious (an effect is dropped—a free parameter becomes a fixed parameter) (Klein, 2011).

The hypotheses were tested using structural equation modeling (SEM) techniques. The adequacy of the proposed conceptual model and its structural relationships was analyzed using PROC CALIS, which uses maximum likelihood

(ML) for the structural model. These SEM structural estimation methods tested if the predicted relationships among the latent constructs reasonably fit the data.

Measures. The selection of measures is important to ensure proper modeling. Score reliability is important in SEM. The use of multiple measures for the latent construct called “Affect” may reflect more aspects of “affect” and the reliability of factor measurement tends to be higher with multiple indicators (Klein, 2011). The latent factor diabetes social support (DSS) (F1), was measured using six DCP indicator scales of social support needs being met (F1A–F1F). The latent factor knowledge (F2) was comprised of three scales, 2 DCP sections and LAD (F2A-F2C). The latent factor for affect (F3) was developed using three measurement instruments; the first was PAID, which measures distress or anxiety, the second was the PHQ-2 and/or PHQ-9 focused on measuring depression, and the third measure was “positive or negative attitude” from the DCP instrument (F3A-F3C). The latent factor for self-efficacy (F4) was created using three scales, two DCP sections on care ability and self-management, and the DES score (F4A-F4C). The dependent measures were three separate self-management behaviors (diet, exercise, competency) and A1c (Y1-Y4). There was a total of eight exogenous characteristics studied (X1-X8) and the covariance was estimated between these eight exogenous variables and each factor (F1-F4) and each self-management behavior and A1c. (See Figure 10)



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Figure 10. SEM showing the full structural model with the exogenous characteristics (X1-X8) under study and the measurement indicators (dark boxes) used to construct the latent factors (ovals) of diabetes social support, knowledge, affect and self-efficacy. Dependent variables are shown as Y1 – Y4. Error variances are shown with a D (disturbance) or E (error).

Model 3 T0 Original Hypothesized estimation results. The original hypothesized model contained one exogenous latent factor (diabetes social support) and three endogenous latent factors (affect, knowledge, and self-efficacy). Exogenous observed variables for demographic, socioeconomic, and illness-related characteristics: age, gender, ethnicity, educational level, employment status, insulin use, duration of diabetes, and marital status were included in the model. Both literature review and preliminary analysis showed systematic relationships between the exogenous characteristics and the model indicator variables.

To examine the TO (baseline) original full model (Model 3) and related hypotheses, diabetes social support, knowledge, and affect were latent constructs that a priori were predicted as directly relating to self-efficacy and indirectly to self-management. The model also represented the hypothesis that self-efficacy was a mediator for diabetes social support, knowledge, and affect to self-management behaviors (SMB).

A covariance matrix data set ($n = 564$) used 24 observed indicator variables with four latent factors (DSS, knowledge, affect, and self-efficacy) and 8 exogenous variables, for a total of 112 parameters and 300 observations = 188 degrees of freedom ($300 - 112 = 188$). Four indicators, one for each latent factor, were normalized for scaling purposes ($=1$).

Direct and total effects of latent constructs. Figure 11 represents the coefficient estimates for Model 3 (TO – Original Hypothesized), and it is labeled with the parameters quantifying the direct and indirect pathways through which the exogenous characteristics and latent constructs of DSS, knowledge and affect influence self-efficacy and self-management for each of the dependent variables. The unstandardized, standard error, and standardized results are shown for each direct effect.

Significant unstandardized direct effect from affect to knowledge is $\beta = .281$, $SE = .14$, $p < \text{value } .05$, from knowledge to self-efficacy ($.659$, $SE = .13$, $p < \text{value } .001$), diabetes social support to self-efficacy ($.602$, $SE = .12$, $p < \text{value } .001$).

The direct effects from DSS to affect, affect to SE, affect to SM, knowledge to SM, DSS to SM were not significant and are represented by a dashed line.

The standardized direct effects are reported for each of the factors, but using ML, significance is not attributed to a standardized result. The unstandardized path coefficients cannot be compared directly, but the standardized coefficients can be compared as they are scaled. For example, the standardized coefficients for the direct effect from diabetes social support to self-efficacy is $\beta = .220$ and direct effect from knowledge to self-efficacy is $\beta = .589$. This indicates the absolute size of the standardized direct effect of knowledge on self-efficacy is approximately three times that of diabetes social support. That is, a level of self-efficacy one full standard deviation above the mean predicts a knowledge level increase of just over .59 standard deviations above the mean, holding affect constant. Likewise, a level of self-efficacy one full standard deviation above the mean, controlling for knowledge and affect, is associated with an increased diabetes social support level of .22 standard deviations above the mean.

In SEM, the exogenous factors have error variances (E) and the endogenous factors have disturbance variances (D) associated with them. Analyzing the disturbance (for the endogenous) variable for self-efficacy (standardized) was .238, representing the unexplained variance, or an R^2 of $1 - .238 = .762$ or 76.2% explained variance. The disturbance variance for self-management (unstandardized) results are 1.57 or an $R^2 = 1.0 - 1.57 = .237$ or 23.7%. This method can be used for

interpreting the explained variance of the other model factors' error or disturbance variances (See Figure 11).

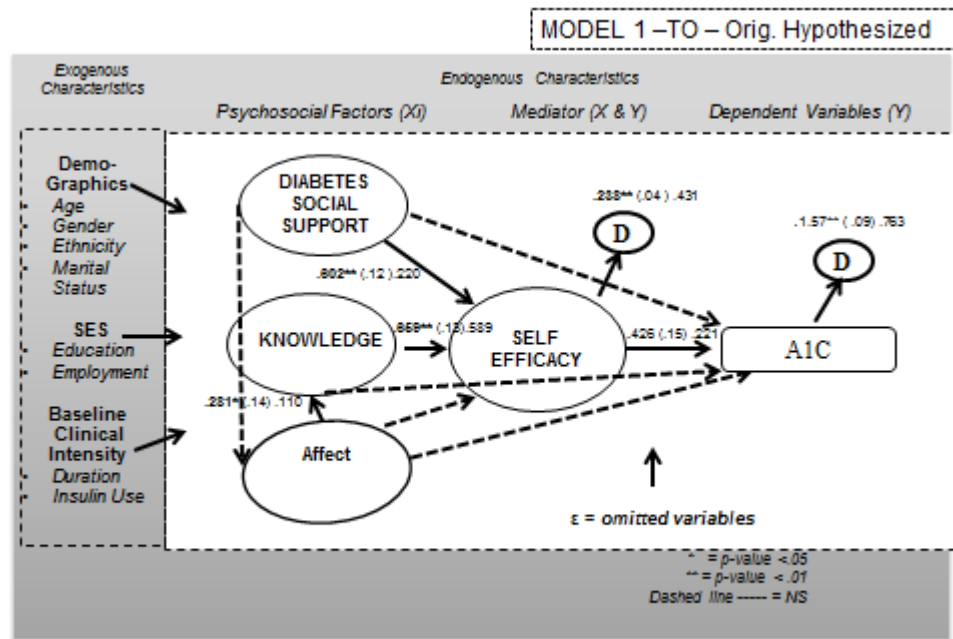


Figure 11. SEM Model 3 (Original) at T0 (Baseline) results from proposed conceptual model with unstandardized, (SE), standardized direct effect results (N = 564). Model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

Model 3 Fit Analysis: The model converged properly. As expected due to the large sample size, results showed that the chi-square was significant, X^2 (df = 184; n=564) = 396, $p < .000$. The RSMEA estimate at 0.0453, the SRMR at 0.048, the GFI was .94 (Bollen, 1998; Klein, 2011; Steiger 2007). The details of the GOF summary results from Model 3 (T0 Original Full) structural model are available in Table 16. This lack of significance for several pathways indicated a need for model respecification.

Step 5: Model respecification.

During the model respecification phase, after completing the analysis of the measurement and structural model above, variables with nonsignificant factor loadings were omitted from the latent construct and/or moved to another theoretically correct measurement model nested in the partially latent structural regression model.

During the CFA principal components analysis, the originally hypothesized variables for functional social support, marital status and number in household, were determined to be a separate factors. After further measurement and structural analysis, marital status was retained as an exogenous characteristic. Number in household, household income, and BMI were trimmed due to lack of significance.

During the structural modeling analysis, the latent factor “diabetes social support” was respecified. The original latent variable for diabetes social support (DSS) was hypothesized, using three observed score variables from the DCP instrument sections: support needs, support received, and support attitudes. While they were significant during the measurement CFA testing, during the structural model estimation, the parameter estimate or variance of support received (T0_supp_rec_dcp_score) was negative in the SEM modeling, indicating a nonpositive definite covariance component. After extensive analysis of the correlations, measurement variances, and covariance matrix structure, it was determined that the “support received” variable was a Heywood case. A Heywood case is a term defining factor solutions with zero or negative estimates of unique

variance components (Klein, 2011). As directed by the literature, an indefinite matrix solution is not admissible on conceptual grounds with a structural equation model. The model estimates must therefore always be at least semidefinite (Bollen, 1993). Despite there being a possible solution for resolving this Heywood case by obtaining nonnegative uniqueness estimates as was noted after setting the variance for support received to zero, it was determined to review the diabetes social support indicator measures being used (Bollen, 1993). A new diabetes social support (DSS) variable was created using the difference between the participant's response to the original subscale questions for support needs and support received around six specific social support questions to produce better indicator variables. Six new dummy variables called "diabetes social support needs met" (meals, meds, exercise, SMBG, feelings) were created from the subscales of support needs and support received as described previously.

The score from the DCP instrument representing "care ability" was reviewed, and as the questions were more representative of measuring self-efficacy, it was moved from knowledge to the latent SE factor. This transfer was supported through principal component analysis as DES and care ability are highly correlated. Self-care ability asked questions about how well they actually "did" in implementing self-management behaviors. It was moved from self-management behavior (Y) to SE as an indicator as it was highly correlated to care-ability.

The original model identified "education treatment group" as an indicator variable for the latent factor "knowledge." As one of the hypotheses involved

comparing the model to those within the education treatment groups, it was trimmed from knowledge. Readiness to change was originally used as a measure in knowledge and was removed due to concerns with the measure from data collection.

The five self-management behavior and A1c indicators were studied as both a latent factor during the measurement-modeling and structural estimation step. As expected, A1c (clinical outcome) and the other self-management behaviors were identified as loading on two-factors in the principal components analysis. A1c was not included in the self-management principal components analysis. Initially, these indicators were recombined for the full structural modeling analysis. Then they were studied as separate factors during the structural modeling step.

Finally, during the structural modeling step in the Model 3 (original hypothesized), it was determined that there was no direct significance between affect and SE and diabetes social support and affect. During the CFA modeling, there was significance between DSS & knowledge noted, and as this is supported by theory, a connection between them was added. These were trimmed or added from (to) the model as it statistically improved the model using the chi-square difference testing (See Table 16). The model respecification steps referenced above were used to develop the final respecified Model Full T0 (baseline) model for analysis (See Figure 12). The following results section reviews the structural estimation of each self-management behavior and A1c using the respecified model.

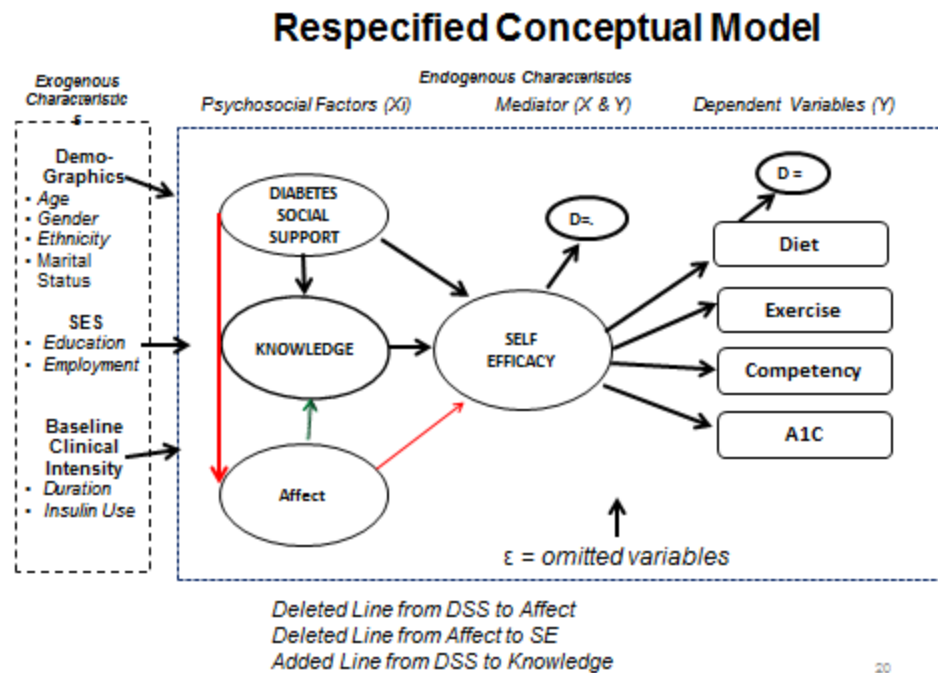


Figure 12. Respecified T0 Model from original proposed conceptual model with lines trimmed between DSS and Affect and from Affect to SE and added between DSS and Knowledge.

Model Comparison Fit Statistics. The original model for A1c was compared to the respecified final model for A1c with parameters of 114 and 112 respectively. The RMSEA was .048 for the original model compared to .043 for the respecified model. The SRMR was .053 for the original model compared to .043, and the GFI indicated better fit for the respecified model at .95 compared to .94 in the original model. The X^2 statistics were both statistically significant questioning the model fit hypothesis. All other GOF fit statistics indicate the respecified model was statistically a slightly better fit. The X^2 difference test results showed $X^2(2) = 17, p \leq .001$, which indicates that the overall fit of the respecified model is statistically better than that of the original model at the .001 level. (See Table 16)

Table 16

Goodness of Fit Statistics RMSEA, SRMR, GFI & χ^2 , comparison of Model 3(original hypothesized) and the respecified Model for A1cs, 564 T0 data for DSS, Knowledge, Affect and Self-efficacy. Results of chi-square difference test comparing the models are noted.

Fit Statistics Analysis	# Parameters	# of Variables	RMSEA Estimate (PI)	RMSEA Lower 90% CL	RMSEA Upper 90% CL	Std RM R (SRMR) (AI)	GFI (AI)	χ^2	χ^2 DF	Pr > χ^2	χ^2 Df diff	χ^2 diff Test	Sign
ORIG Model 3-A1c SC & DES	116	25	.048	.043	.054	.053	.936	396	184	0			
Respecified A1C - No R2C	112	24	.043	.036	.049	.044	.947	.379	188	0	2	17	P=.001

Hypothesis Testing Results.

In the following sections, the results using SEM estimation ML techniques are reported (See Figures 13-16 and Tables 17-20). The first results section displays the model and its estimated direct effect results (unstandardized, SE, and standardized) for each self-management behavior individually as the dependent variable. Model 4 featured diet (Figure 13); Model 5 exercise (Figure 14); Model 6 competency (Figure 15); and Model 7 A1c with SES (Figure 16). Secondly, the a priori hypotheses (1-2) were evaluated using the results from the respecified models. The third section of results evaluated a priori hypothesis 3.

Results Part 1: Direct effects of Models 4-7. The overall respecified final models estimated 112-116 free parameters using 24-25 variables (See Table 21).

The respecified structural models, Models 4-7, display the structural model results for the unstandardized (standard error) and standardized direct effect values. The lines in the figures represent the coefficient estimates for direct effects between the psychosocial, self-efficacy, and self-management latent constructs for each self-management behavior and A1c. Nonsignificant values are noted with a dashed (----) line. The corresponding table shows the decomposition of the total, direct and indirect unstandardized effects, along with the total and direct standardized effect results (See Tables 17-20).

Model 4 (Diet). The respecified conceptual model with diet as the dependent variable was estimated and results are reported in Figure 13 and Table 17. There are positive and statistically significant direct effects on self-efficacy for both knowledge ($\beta = .488^{**}$ p value $<.001$) and diabetes social support ($\beta = .488^{**}$ p value $<.001$). There are positive and statistically significant direct effects on knowledge from both diabetes social support ($\beta = .597^{**}$ (p value $<.001$) and affect ($\beta = .297^{*}$ (p value $<.05$). There is a positive and significant direct effect from self-efficacy to self-management ($\beta = .049^{*}$ p value $<.05$).

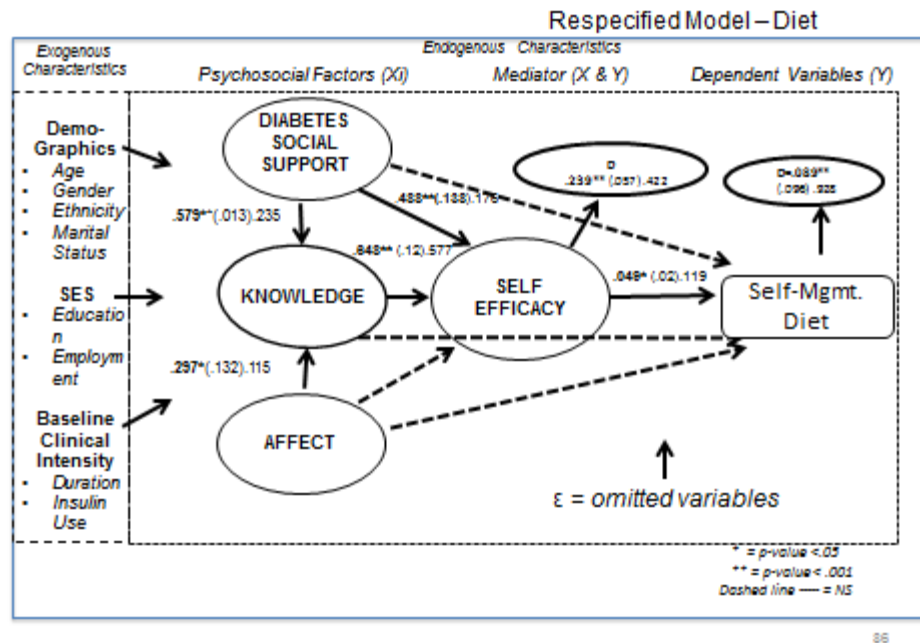


Figure 13. SEM ML (n=564) results from respecified final T0 model with Diet as the self-management behavior with direct effect results in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

For example, the unstandardized direct effect of diabetes social support on self-efficacy is $\beta = .488$. This means that a one-point increase on the diabetes social support variable predicts a .488-point increase on the self-efficacy variable, controlling for knowledge. The estimated standard error for this direct effect is .138 (see Table 17), so $z = .488/.138 = 3.536$ ($p < .01$ with two-tailed statistical significance). Other unstandardized path coefficients were interpreted in the same manner (Klein, 2011).

The variables or measurement indicators do not have the same scale; thus, the unstandardized path coefficients cannot be directly compared. However, this is

possible when reviewing the standardized path coefficients, which are also reported in Figure 13 and Table 17. (Note: there are no standard errors for the standardized estimates (scale=1); as with ML estimation, there is no information about statistical significance with the standardized results). In reviewing the standardized coefficient for diabetes social support \rightarrow self-efficacy, it is $\beta = .176$ compared to knowledge \rightarrow self-efficacy is $\beta = .577$. The inference is that absolute size of the standardized direct effect of knowledge on self-efficacy is about four times that of diabetes social support. Results for the other standardized direct effects in the model can be interpreted in a similar way (Klein, 2011).

The exogenous characteristics with significant effect on diet self-efficacy included age ($\beta = 1.62$ $p < \text{value } .001$), gender ($\beta = .20$ $p < \text{value } .001$), educational level ($\beta = -.17$, $p < \text{value } .05$), and insulin use ($\beta = -.23$ $p < \text{value } .001$). Ethnicity, employment status, duration of diabetes, and marital status are not significant. The detailed coefficients for the unstandardized and standardized direct and total effects on self-efficacy and self-management are described in the table below.

In the table below, the direct effects and disturbance variances are included. The disturbance variances (standardized result) reflect the unexplained variability for each endogenous variable. For example, the standardized result for self-efficacy is .422, which is equal to the ratio of the model disturbance variance over the observed variances or the proportion of observed variance in self-efficacy that is not explained by its presumed direct cause—knowledge and diabetes social support. The R^2 or proportion of explained variance for self-efficacy is $1 - .422 = .578$ or the

model in Figure 13 explains 58% of the total variance for self-efficacy. The estimated disturbance variances for the other three endogenous variables are interpreted in the same way. The R^2 values are also available in Table 32. It should be noted that the unstandardized disturbance variances differ statistically significantly from zero at the $p < .01$ level. These results have no value, as it is expected that error variance will not be zero. Exogenous characteristics and model fit statistics for this model are reported in Tables 35 and 36.

Table 17

Maximum likelihood estimates (unstandardized, standard error, and standardized) for partially recursive path model of causes and effects of self-efficacy on self-management, and knowledge, diabetes social support on self-efficacy for diet model.

Indicator	Effects		
	Unst.	SE	Std.
T0 – Diet			
Direct Effects			
Self-efficacy ---> Self-mgmt Diet	.049*	0.020	0.119
Diabetes Social Support ---> Self-efficacy	.488**	0.138	0.176
Knowledge ---> Self-efficacy	.648**	0.118	0.577
Affect ---> Knowledge	.297*	0.132	0.115
Diabetes SS ---> Knowledge	.579**	0.138	0.235
Disturbance Variances			
Self-management –Diet	.089**	0.005	0.927
Self-efficacy	.239**	0.039	0.422
Diabetes social support	.070**	0.010	0.947
Knowledge	.390**	0.081	0.867
Affect	.066**	0.008	0.978
Unstd. = Unstandardized, SE = standard error and Std. = Standardized			

Model 5 (Exercise). The respecified conceptual model with exercise as the dependent variable was estimated and results are reported in Figure 14. There are

positive and statistically significant direct effects on self-efficacy for both knowledge ($\beta = .649$, p value $<.001$) and diabetes social support ($\beta = .494$, p value $<.001$). There are positive and statistically significant direct effects on knowledge from both diabetes social support ($\beta = .579^{**}$ (p value $<.001$) and affect ($\beta = .299^{*}$ (p value $<.05$). There is a positive and significant direct effect from self-efficacy to self-management ($\beta = .182$, p value $<.001$).

For example, the unstandardized direct effect of knowledge on self-efficacy is $\beta = .649^{**}$. This means that a one-point increase on the knowledge variable predicts a .649-point increase on the self-efficacy variable, controlling for affect and diabetes social support. The estimated standard error for this direct effect is .13 (Table 18), so the z score = $.649/.13 = 4.99$ ($p < .0001$ with two-tailed statistical significance) and is strongly significant. Other unstandardized path coefficients in Figure 14 and Table 18 are interpreted in the same manner (Klein, 2011).

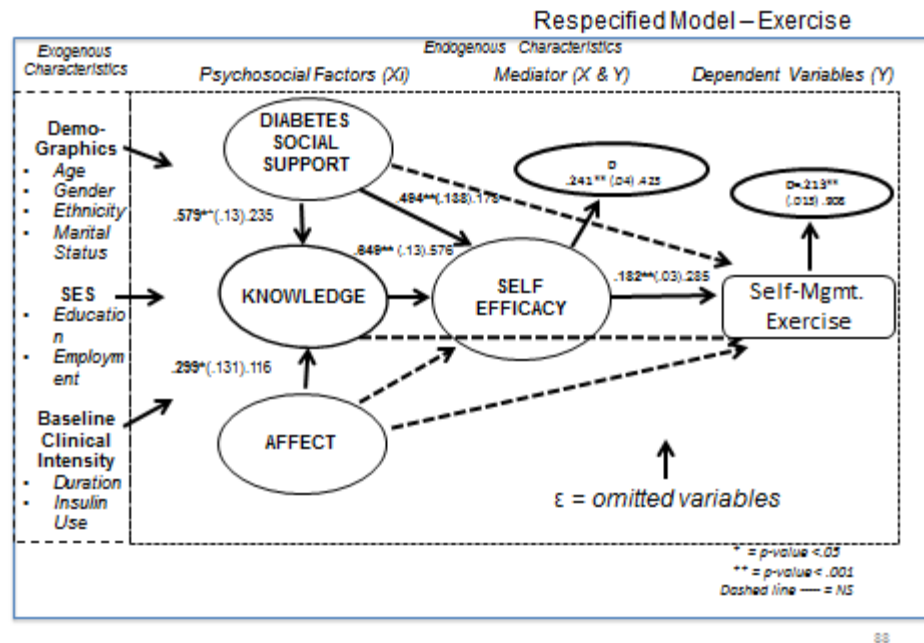


Figure 14 . SEM ML (n=564) results from respecified final T0 model with Exercise as the self-management behavior with direct effect results in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

In the table below, the direct effects and disturbance variances are included.

The disturbance variances (standardized result) reflect the unexplained variability for each endogenous variable. For example, the standardized result for self-efficacy is .423, which is equal to the ratio of the model disturbance variance over the observed variances or the proportion of observed variance in self-efficacy that is not explained by its presumed direct causes—affect and diabetes social support. The R^2 or proportion of explained variance for self-efficacy is $1 - .423 = .577$ or the model in Figure 14 explains 58% of the total variance for self-efficacy. The estimated disturbance variances for the other endogenous variables are interpreted in the same

way. The R^2 values are also available in Table 32. The effect of the exogenous characteristics and model fit statistics for this Model 5 (Exercise) are reported in Tables 35 and 36.

Table 18

Maximum likelihood estimates (unstandardized, standard error and standardized) for partially recursive path model of effects of exercise, affect, and knowledge, diabetes social support on self-efficacy.

Indicator	Effects		
T0 – Exercise	Unst.	SE	Std.
	Direct Effects		
Self-efficacy ---> Self-management	.182**	0.031	0.285
Diabetes Social Support ---> Self-efficacy	.494**	0.138	0.178
Knowledge ---> Self-efficacy	.649**	0.128	0.576
Affect ---> Knowledge	.299*	0.132	0.116
Diabetes SS ---> Knowledge	.579**	0.130	0.235
	Disturbance Variances		
Self-management –Exercise	.213**	0.096	0.908
Self-efficacy	.390**	0.057	0.423
Diabetes social support	.070**	0.010	0.947
Knowledge	.390**	0.040	0.867
Affect	.066**	0.008	0.978

Model 6 (Competency). The respecified conceptual model with competency for daily SMBG testing, daily aspirin, and not smoking as the self-management dependent variable was estimated and results are reported in Figure 15. There are positive and statistically significant direct effects on self-efficacy for both knowledge ($\beta = .647$, p value $<.001$) and diabetes social support ($\beta = .491$, p value $<.001$). There are positive and statistically significant direct effects on knowledge from both diabetes social support ($\beta = .579^{**}$ (p value $<.001$) and affect

($\beta = .296^{**}$ (p value <.001). There is a positive and significant direct effect from self-efficacy to self-management ($\beta = .066$, p value <.05).

For example, the unstandardized direct effect of effect on knowledge is $\beta = .296^{**}$. This means that a one-point increase on the affect variable predicts a .296-point increase on the knowledge variable, controlling for self-efficacy. The estimated standard error for this direct effect is .13 (Table 19), so the z score = $.296/.13 = 2.27$ (The two-tailed P value equals 0.0244 and by conventional criteria; this difference is considered to be statistically significant). Other unstandardized path coefficients in Figure 15 and Table 19 are interpreted in the same manner (Klein, 2011).

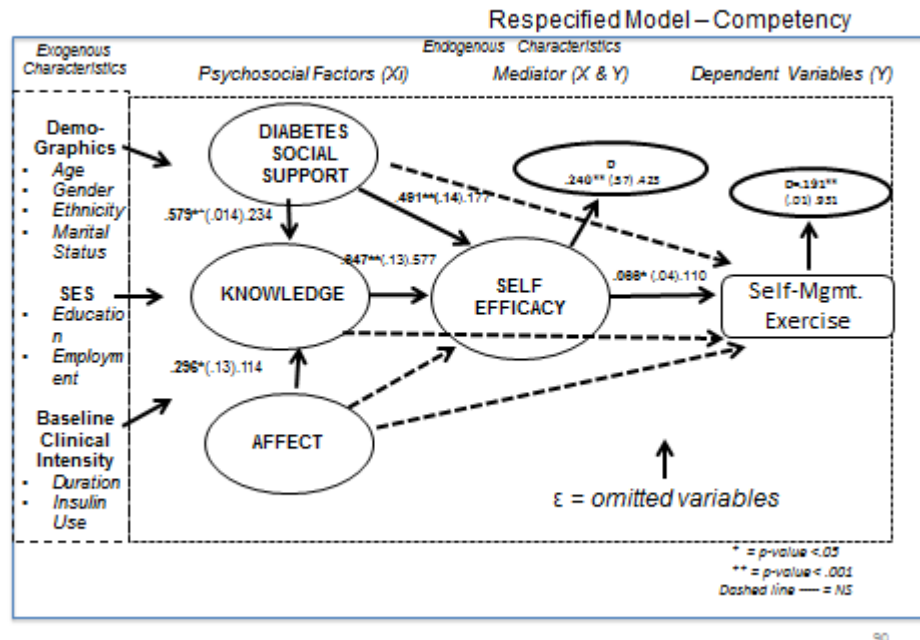


Figure 15. SEM ML (n=564) results from respecified final T0 model with Competency as the self-management behavior with direct effect results in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

In the table below, the direct effects and disturbance variances are included. The disturbance variances (standardized result) reflect the unexplained variability for each endogenous variable. For example, the standardized result for self-efficacy is .423**, which is equal to the ratio of the model disturbance variance over the observed variances or the proportion of observed variance in self-efficacy that is not explained by its presumed direct causes—knowledge and diabetes social support. The R^2 or proportion of explained variance for self-efficacy is $1 - .423 = .577$ or the model in Figure 15 explains 58% of the total variance for self-efficacy. The estimated disturbance variances for the other endogenous variables are interpreted in the same way. The R^2 values are also available in Table 32. The effect of the exogenous characteristics and model fit statistics for Model 6 (Competency) are reported in Tables 35 and 15.

Table 19

Maximum likelihood estimates (unstandardized, standard error and standardized) for partially recursive path model of causes and effects of competency on self-management, affect, and knowledge, and diabetes social support on self-efficacy.

Indicator	Direct Effects		
T0 -Final Competency	Unst.	SE	Std.
Direct Effects			
Self-efficacy ---> Self-management	.066*	0.040	0.110
Diabetes Social Support ---> Self-efficacy	.491**	0.134	0.177
Knowledge ---> Self-efficacy	.647**	0.139	0.577
Affect ---> Knowledge	.296*	0.131	0.114
Diabetes SS ---> Knowledge	.597**	0.134	0.240
Disturbance Variances			
Self-management -Final Competency	.191**	0.011	0.931
Self-efficacy	.240**	0.039	0.423
Diabetes social support	.070**	0.010	0.947

Knowledge	.309**	0.080	0.868
Affect	.066**	0.007	0.978

Model 7 (A1c with SES). The respecified conceptual model with A1c with SES as the dependent variable was estimated and results are reported in Figure 17. There are positive and statistically significant direct effects on self-efficacy for both knowledge ($\beta = .648$, p value $<.001$) and diabetes social support ($\beta = .482$, p value $<.001$). There are positive and statistically significant direct effects on knowledge from both diabetes social support ($\beta = .579^{**}$ (p value $<.001$) and affect ($\beta = .296^{*}$ (p value $<.05$)). There is a positive and significant direct effect from self-efficacy to self-management ($\beta = .391$, p value $<.001$). The direct effects of affect, diabetes social support, and knowledge on self-management were $\beta = -.083$; $\beta = -.272$; and $\beta = -.053$ respectively, and were not significant.

The unstandardized direct effect of knowledge on self-efficacy is $\beta = .648^{**}$. This means that a one-point increase on the knowledge variable predicts a .648-point increase in self-efficacy, controlling for affect and diabetes social support. The estimated standard error for this direct effect is .11 (Table 20), so the z score = $.648/.11 = 5.89$ (The two-tailed P value equals 0.001, and by conventional criteria, this difference is considered to be statistically significant). Other unstandardized path coefficients in Figure 16 and Table 20 are interpreted in the same manner (Klein, 2011).

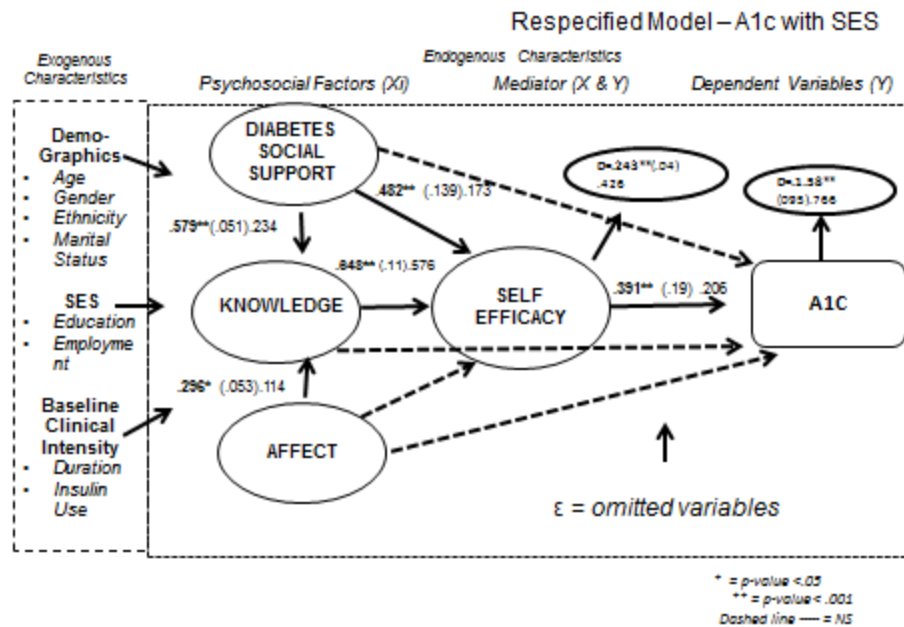


Figure 16. SEM ML (n=564) results from respecified final T0 model with A1c with SES as the self-management behavior with direct effect results in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

In the table below, the direct effects and disturbance variances are included.

The disturbance variances (standardized result) reflect the unexplained variability for each endogenous variable. For example, the standardized result for self-management is .766, which is equal to the ratio of the model disturbance variance over the observed variances or the proportion of observed variance in self-management that is not explained by its presumed direct causes: diabetes social support, knowledge, affect, and SE. The R^2 or proportion of explained variance for self-efficacy is $1 - .766 = .234$ or the model in Figure 16 explains approximately 23% of the total variance for self-management. The estimated disturbance variances

for the other endogenous variables are interpreted in the same way. The R^2 values are also available in Table 32. The effect of the exogenous characteristics and model fit statistics for Model 7 (A1c with SES) are reported in Tables 20 and 34.

Table 20

Maximum likelihood estimates (unstandardized, standard error and standardized) for partially recursive path model of causes and effects of affect, knowledge, and diabetes social support on self-efficacy, and self-management and self-efficacy on self-management.

Indicator	Direct Effects		
T0 – Final A1c with SES	Unst.	SE	Std.
Direct Effects			
Self-efficacy ---> Self-management	0.391**	0.185	0.206
Diabetes Social Support ---> Self-efficacy	.482**	0.139	0.173
Knowledge ---> Self-efficacy	.648**	0.111	0.576
Affect ---> Knowledge	.296*	0.053	0.114
Diabetes SS ---> Knowledge	.579**	0.051	0.234
Diabetes SS ---> Self-management	-.015	0.020	-0.051
Knowledge ---> Self-management	0.292*	0.030	0.022
Affect ---> Self-management	0.009	0.009	-0.015
Disturbance Variances			
Self-management -A1c with SES	1.58**	0.095	0.766
Self-efficacy	.243**	0.040	0.426
Diabetes social support	.070**	0.010	0.947
Knowledge	0.392**	0.089	0.868
Affect	0.066**	0.007	0.978

Model Comparison Fit Statistics. The results from the model fit statistics for the final respecified Models 4 – 7 are displayed (Table 21). The chi-square model test statistics are significant in all of the models, thus the exact fit hypothesis is rejected (the null hypothesis states is if the chi-square model test statistic is not statistically significant, the exact fit hypothesis cannot be rejected). In further

review of the literature, this is not unexpected due to the large sample size. All other fit statistics, RMSEA, SRMR, and GFI, are generally favorable and meet acceptable levels for considering the sample data as an approximate fit to the proposed conceptual model data.

The fit statistics for the respecified A1c with SES model, which included lines to self-management compared to the same model without lines between the psychosocial factors directly to self-management, was conducted. The X^2 difference test results showed $X^2_{(df=3)} = 1.50$ and is not significant, which indicates that the overall fit of the respecified model with lines to self-management or not having the lines to self-management are not statistically different models (see Table 21).

Table 21

Goodness of Fit Statistics RMSEA, SRMR, GFI & X^2 ($n = 564$ T0 data) for the respecified models of diet, exercise, competency and A1c with SES. Results of chi-square difference test comparing the A1c respecified model with lines to SM and without lines to SM is reported.

Respecified Structural Models (n=564)	# Parameters	# of Variables	RMSEA Estimate (PI)	RMSEA Lower 90% CL	RMSEA Upper 90% CL	Std RM R (SRMR) (AI)	(GFI) (AI)	Chi-Square	Chi-Square DF	P > Chi-Square	X^2 Df Diff	Significance
Model 4 - Final Diet T0	112	24	.043	.037	.049	.045	.940	379	188	0		
Model 5 - Final Exercise T0	112	24	.045	.037	.051	.045	.946	389	188	0		

Model 6 - Final COMP T0	112	24	.044	.037	.049	.045	.946	384	188	0			
Model 7 - Final A1c with SES no lines T0	112	24	.043	.036	.049	.044	.947	379	188	0	-3	1 . 5	NS

Part 2: Hypothesis Testing.

Hypothesis 1A): It was hypothesized that increased (decreased) affect, as measured by more distress, depression, and negative attitude, would directly influence and be associated with decreased (increased) knowledge.

Affect → Knowledge (Accepted)

Increasing affect is negative, as the observed measures increase for anxiety, depression, and negative attitude. There were consistent significant direct unstandardized effects by the latent construct affect on knowledge for each of the self-management behaviors and for A1c (β ranges = 0.266-299, p value = .05) (See Table 22). Therefore, the hypothesis is supported for a direct effect at p value $\leq .05$ level between affect and knowledge for diet, exercise, competency and A1c with SES.

The total effects are the sum of all direct and indirect effects of one variable on another. The total effect of affect is through knowledge, as there are no indirect effects. For example, the standardized total effects of effect on knowledge (β ranges = 0.114 - 116) approximates the part of their observed correlation due to presumed causal relations.

Table 22

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Affect ---> Knowledge for each self-management behavior, A1c with SES model. Standard errors are included.

Effect - Unstandardized					Effects Standardized	
Affect ---> Knowledge						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.297*	0.132	.297*	NE	.115	.115
Exercise	.299*	0.132	.299*	NE	.116	.116
Competency	.296*	0.131	.296*	NE	.114	.114
A1c with SES & Lines	.296*	0.053	.296*	NE	.114	.114

Hypothesis 1B): Does diabetes social support directly influence affect?

Diabetes Social Support → Affect (Rejected)

It was hypothesized that increased (decreased) diabetes social support would directly influence and be associated with decreased (increased) affect. This hypothesis was rejected, as there was no significant direct effect by the latent construct diabetes social support on affect, as the $\beta = -0.001$, p value = .89 in the original Model 3. This pathway was trimmed in the respecified model.

Diabetes Social Support → Knowledge (Accepted)

In the respecified model, a pathway was added between DSS and Knowledge, as it aligns with theory. A new hypothesis was added stating that increased (decreased) diabetes social support would directly influence and be associated with increased (decreased) knowledge. This hypothesis was accepted, as there was significant direct effect between DSS and Knowledge. A significant

direct effect by the latent construct diabetes social support was associated positively with increased knowledge in all dependent variables (diet, exercise, competency, A1c with SES ($\beta = .579$, p value $<.001$). This result suggests a strong positive link between these two constructs, and the hypothesis is accepted (See Table 23).

Table 23

Decompositions for Total, Direct and Indirect Effects of Diabetes Social Support --- > Knowledge for each self-management behavior, (Unstandardized) and Total and Direct Effects (Standardized) Standard errors are included.

Effect - Unstandardized					Effects Standardized	
DSS ---> Knowledge						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.579**	0.138	.579**	NE	0.235	0.235
Exercise	.579**	0.131	.579**	NE	0.235	0.235
Competency	.579**	0.134	.579**	NE	0.234	0.234
A1c with SES & Lines	.579**	0.051	.579**	NE	0.234	0.234

Hypothesis 1C): Do the latent psychosocial factors of affect, knowledge, and social support directly influence self-efficacy?

Affect → Self-efficacy (Rejected for Direct Effects, Accepted for Total Effects)

- a. It was hypothesized that increased (decreased) affect would directly influence and be associated with decreased (increased) self-efficacy. There were no significant direct effects by the latent construct effect on latent self-efficacy in any of the dependent variables for the respecified model (range of $\beta = .091$ to $.102$). Please note that the total effects were significant between affect and self-efficacy in all dependent variables, indicating affect directly through knowledge is impacting SE indirectly. The total effects

between affect and self-management for all dependent variables was significant, again indicating affect is directly influencing knowledge and indirectly influencing self-efficacy and self-management (See Table 24).

Table 24

Decompositions for Total, Direct and Indirect Effects (Unstandardized), Total, and Direct Effects (Standardized) of Affect ---> Self-efficacy for each self-management behavior and A1c with SES model. Standard errors are included.

Effect - Unstandardized					Effects Standardized	
Affect ---> SE						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.193*	.09	NE	.193*	.066	NE
Exercise	.194*	.09	NE	.194*	.079	NE
Competency	.192*	.09	NE	.192*	.066	NE
A1c with SES & Lines	.192*	.09	NE	.192*	.067	NE

Knowledge → Self-efficacy (Accepted for Direct and Total Effects)

- b. It was hypothesized that increased (decreased) knowledge would directly influence and be associated with increased (decreased) self-efficacy. A significant direct effect by the latent construct knowledge was associated positively with increased self-efficacy in all dependent variables (diet, exercise, competency, and A1c with SES (β ranges = .647 to .649, p value <.001). This result suggests a strong positive link between these two constructs, and the hypothesis is accepted (see Table 25).

Table 25

Decompositions for Total, Direct and Indirect Effects (Unstandardized), Total, and Direct Effects (Standardized) of Knowledge ---> Self-efficacy for each self-management behavior and A1c with SES model. Standard errors are included.

Effect - Unstandardized					Effects Standardized	
Knowledge ---> SE.						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.648**	.125	.648**	NA	.577	.577
Exercise	.649**	.130	.649**	NA	.576	.576
Competency	.647**	.123	.647**	NA	.576	.576
A1c with SES & Lines	.648**	.123	.648**	NA	.576	.576

Diabetes Social Support → Self-efficacy (Accepted for Direct & Total Effects)

- c. It was hypothesized that increased (decreased) diabetes social support factors would directly influence and be significantly associated with increased (decreased) self-efficacy. The results show support for this hypothesis, with a positive significant direct effect of diabetes social support on self-efficacy (β ranges = .857 - .870, p value = .001). There is evidence to show that increasing diabetes social support increases positive self-efficacy. Thus, hypothesis c is accepted (See Table 26).

In this hypothesis analysis, it is noted that the direct effects are significant. The total effects are different from the direct effects, indicating there are indirect effects as well. The unstandardized total effect of diabetes social support on self-efficacy for the A1c model is the sum of the unstandardized direct effect ($\beta = .482$, p value $\leq .001$) and the indirect effect ($\beta = .375$, p value $\leq .001$) through knowledge

(Figure 16). The total unstandardized effects are calculated by the sum of the direct effect and its indirect effect via knowledge:

$$.482 + (.579) (.648) = .482 + .375 = .857^{**} \text{ (total effect)}$$

The total unstandardized effect for diabetes social support to self-efficacy is $\beta = .857$, $p \text{ value} \leq .001$, which means that for every one-point increase on the diabetes social support variable in its original metric, about a .86 increase in self-efficacy is expected.

Standardized estimates of total effects are calculated the same way using the standardized coefficients and are interpreted as path coefficients. The total standardized effect of DSS to SE ($\beta = .308$, $p \text{ value} \leq .001$) means that increasing diabetes social support by one standard deviation increases self-efficacy by .31 standard deviations via all the presumed direct and indirect causal links between these two variables. Results for the other unstandardized and standardized total effects in the model can be interpreted in a similar way.

Table 26

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Diabetes Social Support---> Self-efficacy for each self-management behavior, A1c with SES and A1c without SES model. Standard errors are included.

DSS ---> SE	Effect - Unstandardized				Effects Standardized	
	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.864**	0.139	.488**	.375**	0.316	0.176
Exercise	.870**	0.138	.494**	.376**	0.313	0.178
Competency	.857**	0.139	.491**	.376**	0.312	0.177

A1c with SES & Lines	.863**	0.139	.482*	.376**	0.308	0.173
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Hypothesis 1D): It was hypothesized that affect, knowledge, and social support would not directly influence self-management.

Affect ≠ Self-management. (Accepted for Direct and Indirect Effects)

- a. It was hypothesized that affect, knowledge, and social support would not directly influence self-management.

There were no significant direct effects by the latent construct effect on self-management in any of the dependent variables for the respecified model. Please note that the total effects were significant between affect and self-management in exercise and A1c with SES parameters, indicating affect through knowledge and self-efficacy, is influencing SM indirectly (See Table 27).

Table 27

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Affect ---> Self-management for each self-management behavior and A1c with SES model. Standard errors are included.

Effect - Unstandardized					Effects Standardized	
Affect ---> Self-Mgmt.						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	NE	NE	NE	NE	NE	NE
Exercise	.035*	.02	NE	.035*	.019	NE
Competency	NE	NE	NE	NE	NE	NE
A1c with SES & Lines	.075*	.04	NE	.075*	.014	NE

Knowledge ≠ Self-management (Accepted for Direct Effects & Indirect Effects)

It was hypothesized that increased (decreased) knowledge would not directly influence increased (decreased) self-management. No significant direct

effect by the latent construct knowledge was associated positively with increased self-management in any of the dependent variables (diet, exercise, competency, and A1c with SES). This result suggests the hypothesis of no direct link between these two constructs can be accepted (see Table 28).

Table 28

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Knowledge ---> Self-management for each self-management behavior and A1c with SES model. Standard errors are included. (NE = No effect)

Knowledge ---> Self-Mgmt.	Effect - Unstandardized				Effects Standardized	
	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.032*	0.015	NE	.032*	0.069	NE
Exercise	.117**	0.033	NE	.117**	0.164	NE
Competency	.043*	0.021	NE	.043*	0.064	NE
A1c with SES & Lines	.253**	0.074	NE	.253**	0.119	NE

Diabetes Social Support \neq Self-management (Accepted)

It was hypothesized that increased (decreased) diabetes social support would not directly influence increased (decreased) self-management. No significant direct effect by the latent construct diabetes social support was associated with self-management in any of the dependent variables (diet, exercise, competency or A1c with SES). This result suggests the hypothesis of no direct link between these two constructs can be accepted (See Table 29).

Please note that the total effects were significant between diabetes social support and self-management in diet, exercise, competency and A1c with SES models, indicating DSS is influencing SM indirectly through knowledge and SE.

Table 29

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Diabetes Social Support---> Self-management for each self-management behavior and A1c with SES model. Standard errors are included.

Effect - Unstandardized					Effects Standardized	
DSS ---> Self-Mgmt.						
Time Period =T0 (Parameter/Effect)	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.043*	0.019	NE	.043*	0.037	NE
Exercise	.159**	0.037	NE	.159**	0.089	NE
Competency	.058*	0.027	NE	.058*	0.035	NE
A1c with SES & Lines	.335**	0.094	NE	.335**	0.064	NE

This hypothesis was confirmed using Model 4 (respecified) with an alternative model where direct paths from affect, knowledge, and social support were made to self-management and the fit statistics were assessed. The two models (with lines direct from latent constructs of affect, knowledge and diabetes social support to self-management) were compared using SEM analysis. This modeling constituted a test of a rival hypothesis that, if confirmed, would have suggested that the new parameters contribute unique variation to the latent self-management construct. Using chi-square difference statistic, the two models were not significantly different when the lines to SM were used compared to when the lines were constrained.

Reviewing the tables of the Model 4–7 direct effects (unstandardized and standardized) above, there were no significant coefficients attained between affect, knowledge, or diabetes social support directly to self-management. This indicated that they are not directly associated, thus supporting the hypotheses of no direct influence between affect, knowledge, and diabetes social support and self-management.

Hypothesis 1E): It was hypothesized that increased (decreased) self-efficacy would directly influence increased (decreased) self-management behavior(s) (diet, exercise, self-management competency, and A1c score).

Self-efficacy → Self-management (Accepted)

- a. It was hypothesized that increased (decreased) self-efficacy would directly influence increased (decreased) self-management behavior(s) (diet, exercise, self-management competency, and A1c score). As hypothesized, the results show a significant direct effect of self-efficacy on self-management behaviors and A1c score (β 's range = .052 - .391, $p \leq$ value .05 to p value \leq .001) (See Table 30). Reviewing both the total and direct effects for self-efficacy linked to self-management in the models, since they are the same, it indicates support for the hypothesis.

In reviewing Table 30 below, the only significant direct effect and total effect (as it is a partially recursive model and only goes in one direction) on self-management was self-efficacy. For example, in the A1c model, the unstandardized coefficient for the direct effect of self-efficacy on

self-management (A1c score) is .391 (p value <.001). This means a one-point increase on the self-efficacy variable predicts a .39 increase in the self-management A1c score (decrease in A1c score). The standardized coefficient for the direct effect of self-efficacy on self-management A1c score is .206. A level of self-efficacy one full standard deviation above the mean predicts a self-management A1c score just about a .21 standard deviation above the mean.

Table 30

Decompositions for Total, Direct and Indirect Effects (Unstandardized) and Total and Direct Effects (Standardized) of Self-efficacy ---> Self-management for each self-management behaviors & A1c with SES model. Standard errors are included.

SE ---> Self-mgmt. Time Period =T0 (Parameter/Effect)	Effect - Unstandardized				Effects Standardized	
	Total Effects	SE	Direct Effects	Indirect Effects	Total Effects	Direct Effects
Diet	.049*	0.020	.049*	NE	0.120	0.125
Exercise	.182**	0.032	.182**	NE	0.285	0.285
Competency	.066*	0.03	.066*	NE	0.110	0.110
A1c with SES & Lines	.391**	0.086	.391**	NE	0.206	0.206

Hypothesis 2: If it is shown that the psychosocial factors (affect, knowledge, and social support) directly influence self-efficacy, and if it can be shown that self-efficacy directly influences self-management behaviors, is self-efficacy therefore acting as a mediator between the three psychosocial factors and self-management behaviors?

Affect (X) → Self-efficacy (M) → Self-management (Y) = Rejected

Knowledge (X) → Self-efficacy (M) → Self-management (Y) = Accepted

**Diabetes Social Support (X) → Self-efficacy (M) → Self-management (Y) =
Rejected**

Mediation of self-efficacy. A priori it was hypothesized that self-efficacy was a mediator of self-management (the dependent variable-Y2) and not vice versa (Klein, 2011). A mediator effect is predicted when there are direct effects modeled on a Y2 (dependent) variable from other observed variables (from both exogenous and endogenous) and are not significant, then Y1 (self-efficacy) has a dual role (a predictor and a criterion). This effect is assumed to transmit some of the effects of prior variables in the model. Mediation is not statistically defined; thus full and partial mediation can be inferred when a) the effect of the independent variable on the dependent variable was no longer significant after controlling for the mediator (see Model 4), and b) the Sobel test is statistically significant (Sacco, 2007). Statistics such as products of direct effects (indirect effect results) can be used to evaluate a presumed mediational model in SEM (Kenney, 2008).

Step 1: Before the actual test of mediation can take place, the following must be ensured:

a. Diabetes social support, affect, and knowledge are statistically significant predictors of self-efficacy (controlling for exogenous characteristics). As already determined in testing previous hypotheses testing, affect is no longer included in this hypothesis, as it does not significantly impact self-efficacy. The direct effects from diabetes social support and knowledge to self-efficacy (using Model 7 A1c

with SES) were significant; ($\beta_{\text{knowledge A1c}} = .648$, $p \text{ value} = .001$) ($\beta_{\text{diabetes social support A1c}} = .482$, $p \text{ value} = .001$). This test is met for knowledge and DSS.

b. Self-efficacy is a statistically significant predictor of self-management behaviors and A1c with SES (controlling for exogenous characteristics). This test is met for knowledge and DSS ($\beta_{\text{SE} \rightarrow \text{SMA1c}} = .391$, $p \text{ value} = .001$).

c. This third condition for mediation testing requires testing the effect of the independent (X1-X2) variables on the dependent (Y2) variable while constraining for the mediator (M/Y1). Knowledge and DSS must not be statistically significant predictors of self-management (controlling for exogenous characteristics). The total effects between affect ($\beta_{\text{affect A1c}} = .009$, $p \text{ value} = .968$) and self-management and diabetes social support ($\beta_{\text{diabetes social support A1c}} = -0.015$, $p \text{ value} = .948$) and self-management were not significant. The result of the analysis of total effects between knowledge and self-management was significant ($\beta_{\text{knowledge A1c} \rightarrow \text{SM}} = .292$, $p \text{ value} = .05$). Therefore, knowledge is the only psychosocial factor that meets the three tests (a, b and c above) to move into the mediation analysis. The test of mediation ends for DSS and affect as it is concluded that there is no mediation between DSS or affect and SE (Denis, 2010). Completing step 1 above, the next step was to test the mediational hypothesis as follows, in step 2:

Step 2. Use Knowledge to predict self-management (controlling for exogenous characteristics) (as was done in "c" just above). It was observed that knowledge was a statistically significant predictor of self-management ($\beta_{\text{knowledge A1c} \rightarrow \text{SM}} = .292$, $p \text{ value} = .05$ as noted above in Step 1, c). Next, self-efficacy was added

back into the model. The path from knowledge to self-management changed to $\beta_{\text{knowledge A1c} \rightarrow \text{SM}} = -0.053$, $p \text{ value} = .73$ (NS). Since it did not change to zero, it is not “full mediation”. The next test for “partial mediation” was done to determine if the change from “c” to “c'” was big enough to claim partial mediation.

To evaluate partial mediation for the hypothesis of the mediation effect of self-efficacy between knowledge and self-management in SEM, the product ab estimates the unstandardized indirect effect of X on Y_2 through Y_1 (Sobel test) (Baron and Kenny, 1986). The Sobel approximate error test was used to determine the effect of a single mediating variable, M (self-efficacy), defined as a variable that accounts partially for the relationship between the dependent variable Y (self-management) and an independent variable (knowledge (X_2)) (Baron & Kenny, 1986). Sobel a is the unstandardized coefficient for the path $X \rightarrow Y_1$ and SE_a is its standard error, then let b and SE_b , respectively, represent the same thing for the path $Y_1 \rightarrow Y_2$. The SE_{ab} was then calculated to compute the Sobel test results.

Sobel test ($SE_{\text{know}} = 2.41 * (p \text{ value} < .016) = \text{Significant}$

The reported p -values are drawn from the unit normal distribution under the assumption of a two-tailed z -test of the hypothesis that the mediated effect equals zero in the population (± 1.96 are the critical values of the test ratio). The Sobel test is considered a more efficient estimator of the mediated effect for single-level data sets (MacKinnon, 2008).

The results of the above mediational techniques suggest that self-efficacy is a mediator for knowledge, but not for diabetes social support or affect. Therefore,

two of the three hypotheses for mediation by self-efficacy are rejected, and the hypothesis for knowledge being mediated by self-efficacy is accepted.

**Mediation of Knowledge by Affect and Diabetes Social Support
(Accepted for DSS, Rejected for Affect)**

With the respecification of the model, it appears that knowledge may be a mediator for affect and diabetes social support. Based on the mediation method above, the following steps were taken to test this:

Step 1 a. DSS is significant to Knowledge ($\beta_{\text{DSS} \rightarrow \text{Knowledge}} = 0.579$, p value = .001). b. Knowledge is significant to SE ($\beta_{\text{Knowledge} \rightarrow \text{SE}} = 0.648$, p value = .001). c. DSS is significant to SE ($\beta_{\text{DSS} \rightarrow \text{SE}} = 0.482$, p value = .001). Since DSS and knowledge meet the three tests in Step 1, mediation testing may be conducted.

Step 2 a. See Step 1 c above (significant). b. Sobel Testing was conducted using $a = .579$, $b = .482$, $S_a = .051$ and $S_b = .139$. Sobel test results were $\beta_{\text{sobel}} = 2.454$, $SE = .0876$, p value = .014). This indicated that knowledge is a partial mediator for diabetes social support.

Part 3. Hypothesis 3. Is there a statistically significant difference in the direct path between knowledge \rightarrow self-efficacy between the three randomized assigned groups; Model Group 0 (Usual Care), Model Group 1 (Individual Education), and Model Group 2 (Group Education) in T0 to T4?

- a. It was hypothesized that the Group and Individual Education groups who received education interventions would show a statistically positive increase in the path from knowledge to SE than those who did not

receive intervention (usual care) when comparing T0 (Baseline - pre-intervention) to T4 (twelve months - post intervention).

GE & IE > ↑ than UC for Knowledge → SE (T0) to Knowledge → SE (T4) - Rejected

The estimation of the three model groups (usual care, individual education, and group education at T0 (baseline) and T4 (post intervention) were conducted to test this hypothesis. The direct effect path coefficient, its standard error and standard deviation, between knowledge and self-efficacy for T0 was compared to the same coefficient result at T4. The difference between the time periods was statistically assessed for significance using a 2-tailed t-test.

Group 0 (Usual Care, n = 123) when comparing the results from T0 to T4 had a 2-tailed t-test p-value of 0.3020 (not significant). Group 1 (Individual Education, n=246) had a p-value of 0.2767 (not significant) and Group 2 (Group Education, n=243) had a p-value of 0.3757, again not significant. Thus, this hypothesis is rejected (See Table 31).

Table 31

Summary of change in knowledge to SE from T0 to T4 in three control trial treatment groups of usual care, group education and individual education.

Time Period	T0				T4		
Treatment Group	Direct Effect between Knowledge --> Self-Efficacy			2-tailed T-Test (T0 vs T4)	Direct Effect between Knowledge --> Self-Efficacy		
Value	Mean	SD	SE	p-value	Mean	SD	SE
Group 0 - Usual Care, N = 123	0.7723	1.75	0.158		0.8748	2.515	0.227
p-value				0.3020			
Group 1 - Individual Education, N = 246	1.163	3.997	0.255		0.8703	2.47	0.119
p-value				0.2767			
Group 2 - Group Education, N = 243	0.8409	2.989	0.192		1.0849	15.47	0.993
p-value				0.3757			

The above data results and analysis determined the outcomes and findings compared to the original hypotheses. There were findings of interest as it appears that knowledge and diabetes social support direct influence on self-efficacy fit the a priori proposed conceptual model. Affect did not influence self-efficacy directly, but did influence knowledge significantly and indirectly influenced self-efficacy. It appears that knowledge is mediating diabetes social support to self-efficacy, and that self-efficacy is serving as a mediator for knowledge to self-management. There were no significant differences in the direct effects from knowledge to self-efficacy

in the treatment groups (individual or group) compared to the usual care group between T0 and T4.

After evaluating Hypotheses 1-3, there is more information from the structural equation modeling to be gained. The disturbance variances from the latent factors in the models provide information on how well the model is performing. The next section describes the r-squared results and the impact of the exogenous characteristics from the SEM estimation.

Disturbance variances (R-squared) of latent constructs. The estimated disturbance variances (standardized) in each model (called “error” in measurement modeling and “disturbance” for endogenous variables in structural modeling) reflect the unexplained variability for each endogenous variable. By calculating the ratio of the disturbance variance over the observed variance, this ratio explains the proportion of the observed variance that is not explained by its presumed direct cause. For example, the proportion of explained variance for self-efficacy $\beta_{SE} = .343$, p value = .001). Thus, Model 7 in Figure 16 explains $1 - .426 = .574$, or approximately 57% of the total variance in self-efficacy is described by the latent constructs of affect ($r^2 = .02$), knowledge ($r^2 = .13$) and diabetes social support ($r^2 = .053$). In the same way, the proportion of explained variance for self-management outcome (A1c score) is $1 - .766 = .234$, or the model including self-efficacy, diabetes social support, affect, and knowledge, explains 23% of the total variance in self-management. Models 4-7 for each self-management behavior and A1c display consistency in the r-squared values for diabetes social support ($r = .053$), affect ($r =$

.02), knowledge ($r=.16$), and SE ($r = .64 -.66$). The estimated disturbance variances are displayed below in Table 32.

Table 32

Summary of Explained Variance (R^2) for the Latent Factors and Self-Mgmt. (T0).

Disturbance Variances					
R-Square	Diabetes Social Support_t0	Affect_t0	Know_t0	SE_t0	Self_mgmt_t0
Diet	0.053	0.02	0.13	0.58	0.07
Exercise	0.053	0.02	0.13	0.58	0.09
Competency	0.053	0.02	0.13	0.58	0.07
A1c with Lines	0.053	0.02	0.13	0.57	0.23

Exogenous Characteristics. The significant exogenous characteristics noted in the literature were evaluated for their impact on self-efficacy and self-management. Those under study included age, gender, ethnicity, educational level, employment status, duration of diabetes, insulin use, and marital status. There was a significant effect of age on SM for all self-management behaviors and A1c except exercise and SE for all factors. Gender was significant with SE on all factors and with SM except for exercise, competency, and A1c. Race was only significant with SE and SM in A1c with lines model and with SM in competency. Educational level was significant with diet in SE and SM. Employment status and duration of diabetes were only significant with SM in A1c with SES. Insulin use is significant for all factors, and SM is significant for all factors except diet and exercise. Marital status

is not significantly related with SE and only significantly related to SM in diet and A1c with SES.

The contribution of these factors may be explained in the difference between the models tested in the equivalent section, A1c with SES and A1c without SES. The X^2 difference test between these models was 208 df – 114 df = 94 df and X^2 of 425.9 – 250.1 = 175 and statistically significant at the .001 level. The models are significantly different from each other. The model with SES has slightly lower levels of RMSEA and SRMR, suggesting it should be retained (see Table 33).

Table 33

Summary of total effects from demographic, SES, clinical intensity, and marital status exogenous characteristics on diet, exercise, self-care, A1c, and competency models.

Parameter/ p-value * .05 **=.001	Total Effects - DEMOGRAPHIC									
T0 – 564	Diet		Exercise		Self-Care		A1c with SES		Competency	
Demographic Characteristics	SE	Self-Mgmt.	SE	Self-gmt.	SE	Self-Mgmt.	SE	Self-Mgmt.	SE	Self-Mgmt.
Age/100	2.56**	.39**	2.57**	NS	2.48**	2.48**	2.69**	4.44**	2.56**	.642**
Gender (Female)	(.224)**	.056*	(.225)**	NS	(.204)**	(.20)**	(.229)**	NS	(.224)**	NS
White_non	NS	NS	NS	NS	NS	NS	(.151)**	0.448**	NS	.122**
SES										
Education Level	(.277)**	.080*	NS	NS	NS	NS	NS	NS	NS	NS
Employment Status	NS	NS	NS	NS	NS	NS	NS	.270*	NS	NS
Clinical intensity										
Duration of Diabetes	NS	NS	NS	NS	NS	NS	NS	(.26)**	NS	NS
Insulin Use	(.183)**	NS	(.183)**	NS	(.155)**	(.18)**	(.144)**	(.50)**	(.18)**	.928*
Social Status										
Marital Status	NS	.102**	NS	NS	NS	NS	NS	.298*	NS	NS

The next steps in the SEM process are to evaluate if there are theoretically based equivalent models to review and/or rule out the proposed conceptual model. This was recommended knowing there may be many models that could provide different results, and theory-based nested models should be analyzed.

Equivalent model testing (Models 8 & 9).

After a final model is selected, it is recommended that equivalent models should be considered and evaluated in comparison. The TO hypothesized model (Model 1) was compared with two equivalent or alternative models (Model 9 and Model 10). These models were theoretically derived nested models in order to identify the model of best fit and comparison. Sequential X^2 difference tests were used to assess changes in fit between the hypothesized model and competing alternative model (Bollen, 1989a) (see Table 36).

Equivalent Model 1: Model 8 (A1C with no SES). The respecified conceptual model without demographic, SES, clinical intensity exogenous characters using A1c as the dependent variable was estimated, and results are reported in Figure 17. There are positive and statistically significant direct effects on self-efficacy for both knowledge ($\beta = .385$, p value $<.001$) and diabetes social support ($\beta = .747$, p value $<.001$). There are positive and statistically significant direct effects on knowledge from both diabetes social support ($\beta = .625^{**}$ (p value $<.001$) and affect ($\beta = .284^*$ (p value $<.05$). There is a positive and significant direct

effect from self-efficacy to self-management ($\beta = .564$, p value $<.001$). Other unstandardized and standardized path coefficients are noted below in Figure 17.

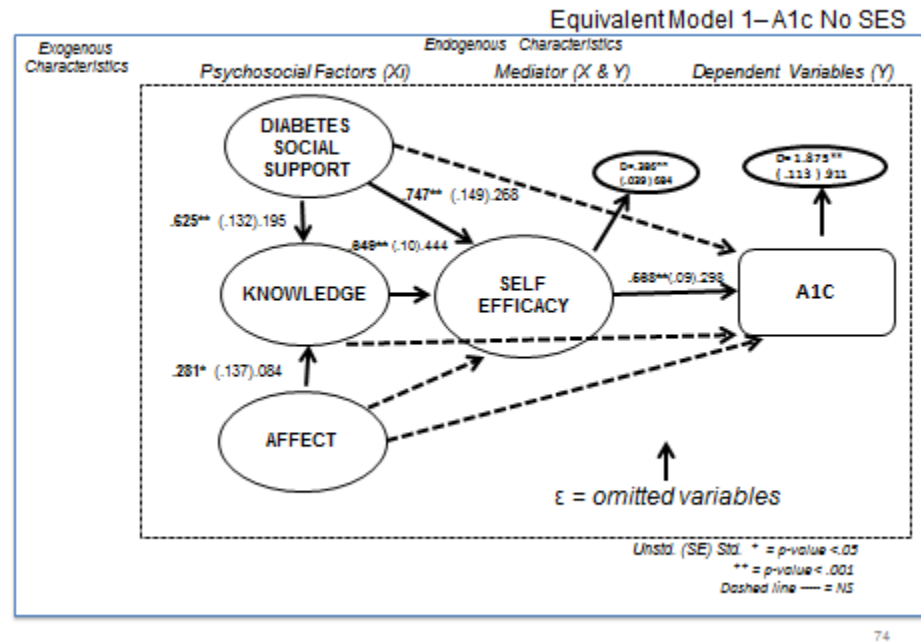


Figure 17. SEM ML ($n=564$) results from respecified final T0 model with A1c no SES with direct effect results in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value $<.05$ and ** = p value $<.01$.

In the table below, the direct effects and disturbance variances are included. The R^2 or proportion of explained variance for self-efficacy is $1 - .684 = .316$, or the model in Figure 18 explains 31% of the total variance for self-efficacy. The effect of the exogenous characteristics and model fit statistics comparing this to Model 7 (A1c with SES) are reported in Tables 34 and 39.

Table 34

Maximum likelihood estimates (unstandardized, standard error, and standardized) for partially recursive path A1c No SES model of causes and effects of self-efficacy on self-management, affect, and knowledge, or diabetes social support on self-efficacy. Disturbance variances are reported for latent factors.

Indicator	Direct Effects		
T0 - A1c No SES	Unst.	SE	Std.
Direct Effects			
Self-efficacy ---> Self-management	.569**	0.134	0.298
Diabetes Social Support ---> Self-efficacy	.747**	0.139	0.269
Knowledge ---> Self-efficacy	.385**	0.100	0.444
Affect ---> Knowledge	.281*	0.132	0.084
Diabetes SS ---> Knowledge	.625**	0.137	0.198
Disturbance Variances			
Self-management -A1c No Lines	1.875**	0.113	0.911
Self-efficacy	.386**	0.039	0.684
Diabetes social support (Exogenous)	NA	NA	NA
Knowledge	.724**	0.064	0.955
Affect (Exogenous)	NA	NA	NA

The results of the X^2 difference test showed that Equivalent Model 1 (Model 8) compared to the Final respecified A1c with SES (Model 7) was statistically significantly different at $X^2_{cf=89} = 167$, p value $\leq .0001$ ($X^2_{m8} = 213$ and df= 114) - X^2_{m7} (379, df= 188). In reviewing the fit statistics, the RMSEA upper limit was $> .05$, making Model 7 the more parsimonious model, and it was retained over Model 8 (see Table 35).

Equivalent Model 2: Model 9 (SE before Knowledge and DSS & A to Knowledge only). For equivalent model 2, self-efficacy was reversed with knowledge and was hypothesized as the mediator (M) to self-management, rather

than SE. A case for mediation by knowledge, rather than SE could be made based on literature, as it has had significance directly to self-management and was already shown positive for diabetes social support in the hypothesis testing. Affect and diabetes social support were directly influencing knowledge as in Model 7.

Direct Effects. Equivalent Model 9 was estimated and the results are reported in Figure 18. There are positive and statistically significant direct effects from SE to knowledge ($\beta = .602$, p value $<.001$) and SE to self-management ($\beta = .441$, p value $<.001$). Unlike Model 7, there are no other statistically significant direct influences on knowledge from either diabetes social support or affect. There is no significant direct effect from knowledge to self-management. All unstandardized, standardized path coefficients of the significant findings are noted below in Figure 18.

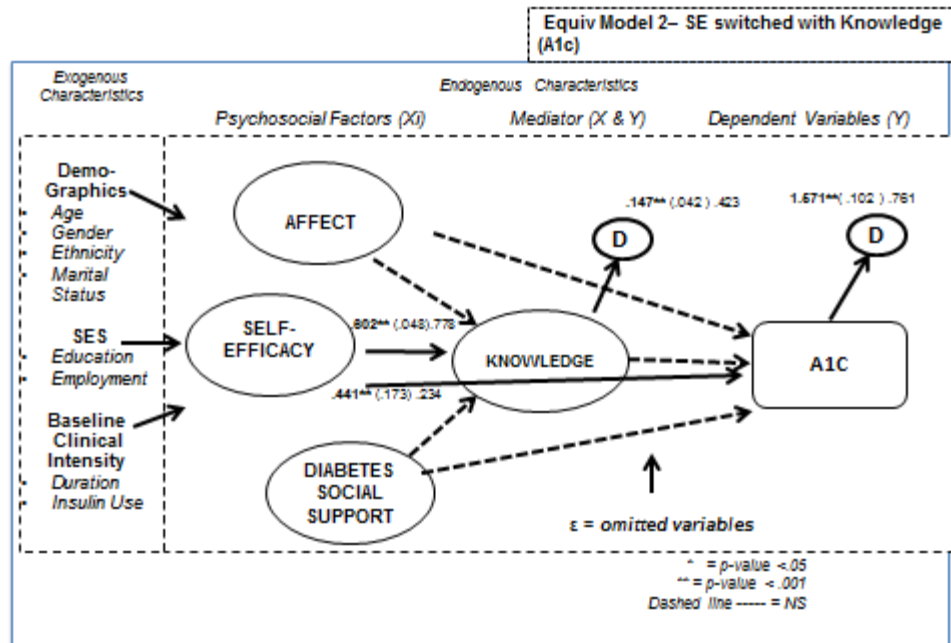


Figure 18. SEM ML ($n=564$) results from equivalent T0 model 9 with self-efficacy moving to before knowledge. Affect and DSS are connected directly to knowledge for A1c as dependent variable. Direct effect results are in this order: unstandardized (SE) standardized results. Unstandardized model parameters in bold and with an asterisk(s) are significant. * = p value < .05 and ** = p value < .01.

Fit Statistics. The results of the X^2 difference test showed Equivalent Model 2 (Model 9) compared to the Final respecified A1c with SES (Model 7) was statistically significantly different at $X^2_{df=21} = 95$ as Model 9 had a $X^2_{m9} = 474$ and $df = 209$) versus Model 7 having a $X^2_{m7} = 379$, $df = 188$). In reviewing the fit statistics, the RMSEA's upper CI was > .05, making Model 7 the more parsimonious model, and it was retained over Model 9 (see Table 35).

Table 35.

Results of the fit statistics and χ^2 test of Equivalent Models 8 and 9 compared to Model 7 (A1c with SES).

Equivalent Models (n=564)	# Parameters	# of Variables	RMSEA Estimate (PI)	RMSEA 90% CL	RMSEA 90% CL	Std RM (SR MR) (AI)	GFI (AI)	χ^2	χ^2 DF	P > χ^2	χ^2 Df Diff	χ^2 diff Test	Sign/N S
Model 7 (Comparison) - Final A1c with SES T0	112	24	.043	.036	.049	.048	.95	379	188	0			
Model 8 - Equivalent Model 1 = Final A1c No SES	37	16	.045	.039	.054	.05	.95	212	99	0	89	167	P value < .001
Model 9 - Equiv. Model 2 A1c - Self-efficacy before Know	116	25	.048	.042	.053	.061	.94	474	209	0	21	95	P value < .001

After analyzing the fit statistics from the equivalent model testing and retaining the final respecified Model 7, the next section describes the sensitivity analysis conducted to evaluate two additional methods for handling missing data compared to the original study using maximum likelihood.

Sensitivity analysis. Due to the missing data in some key variables in T2 and T4, two sensitivity analyses were conducted. The first one used only the participants who had 100% complete data across T0 and T4. This group was analyzed to form the lower end of the sensitivity analysis, as ML will use only those with 100% complete data. A second sensitivity analysis was completed using full information maximum likelihood (FIML), with the 564 raw data rather than covariance data. FIML, also known as direct ML, includes cases with missing data

(Allison, 2003; Schafer and Graham, 2002). Direct ML produces parameter estimates, standard errors, and test statistics that are consistent and efficient (Brown, 2006; Graham, 2009).

Model 10 (208 100% complete) estimated a sensitivity analysis using the data from a subgroup of 208 patients without missing data. The descriptive data for the 208 patients was reviewed and compared to those in the 564 patient data set (See Table 36).

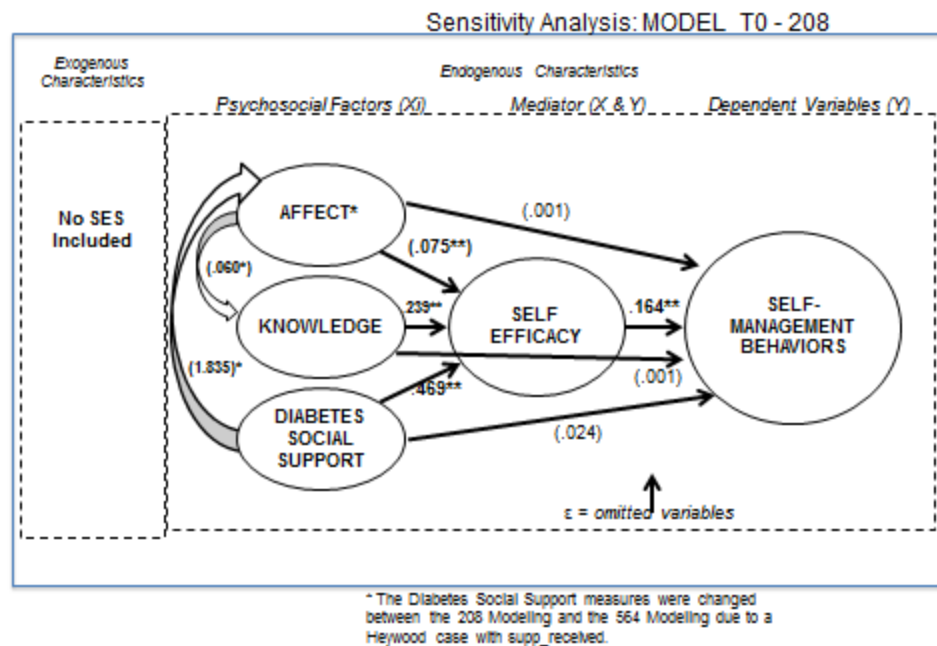
Table 36

Participant Measures at Baseline compared to the SensitivityTest Group. (Includes descriptive statistics for the 208 participants who had 100% complete data across T0 - T4 used for the sensitivity analysis.)

Characteristics	T0-T4 (100% Complete Data = Sensitivity Analysis)	Percent (%) or SD (±)
N (study participants)	208	
Site distribution		
HP/HPMG	152	73%
LCF/ABQ	56	27%
Age (years)	61.77	± 9.4
Sex (women)	93	45%
Race/Ethnicity		
White	161	77.4%
Black/Hispanic/Other	47	22.5%
Education		
<High school & HS grad	41	20%
Some college & >= college grad+	167	80%
Income		
<\$20,000	22	11%
\$20K-\$70,000+	186	89%
Employment		
Working	81	39%

Retired/disabled/other	127	61%
Marital Status ^b		
Married	156	75%
Not married/widowed/separated	52	25%
No. of additional people in household Mean \pm SD	1.43	\pm 1.17
Duration of diabetes, mean \pm SD, years	10.8	\pm 7.27
BMI, mean \pm SD, kg/m ²	34.1	\pm 7.2
Baseline A1c Mean of A1C \pm (SD)	7.93	\pm 1.18

The results from the analysis of the 208 100% complete participants were compared to the overall 564-participant sample (Model 3 using the n= 564-covariance data). The model below displays the direct effects between latent constructs using the original hypothesized model (See Figure 19).



100

Figure 19. Results of the sensitivity analysis using 100% complete (N=208) analysis with original hypothesized data. The diabetes social support measures were changed after this analysis. Parameters in bold and with an asterisk are significant. * = p value < .05 and ** = p value < .01.

A comparison of the direct effects of the latent factors on self-efficacy and self-management from Model 10 are shown in Table 37. The fit testing results were compared also for the three models (See Table 38).

Model 11 (564-FIML, Direct ML). A second sensitivity analysis was estimated using full information maximum likelihood (FIML), also known as maximum likelihood direct method estimation. FIML used the 564 population raw data rather than covariance data. The model showing the direct effects between latent constructs is displayed in Figure 20. Pathways from affect, knowledge, and diabetes social support to SE were statistically significant. The path between affect

to knowledge was significant ($\beta = .060$, p value $< .05$). The path from DSS to affect was not significant. The path from SE to SM was significant ($\beta = .188$, p value $< .001$). The direct paths between affect, knowledge and DSS were not significant.

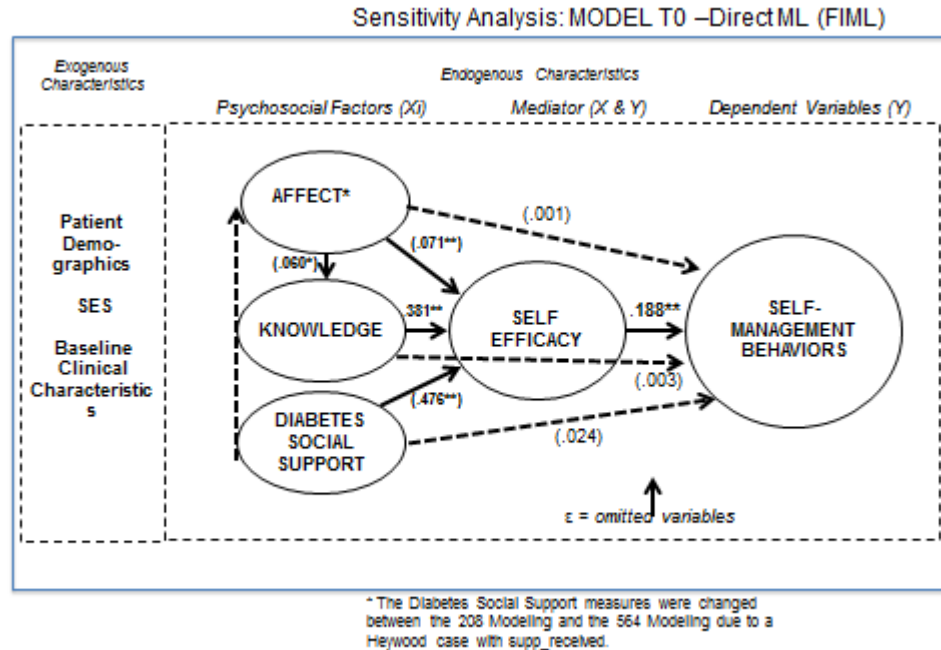


Figure 20. Results of the sensitivity analysis using 564 Raw Data (FIML, Direct ML and N=540) using the hypothesized conceptual model. Parameters in bold and with an asterisk are significant. * = p value $< .05$ and ** = p value $< .01$.

The results of this analysis were compared to Model 8 (Figure 17) and Model 10 above (Figure 19). After the SEM modeling was completed with the 208 analysis and the 564 FIML (raw data) analyses, it was determined that one of the indicator variables for diabetes social support measure, support received, was a Heywood case. For Model 8 (564 cov A1c with no SES) analysis, the diabetes social support indicators were redeveloped using dummy variables comparing the six subscales for support received and support needs. The direct effect on self-

efficacy and self-management coefficients from the structural regression modeling for the sensitivity analyses demonstrates stability in the model, except for the statistical significance of affect → self-efficacy. In Model 8, affect was not statistically significant, whereas it was significant with p value <.001 for both the 208 100% and 564 FIML models. This change in affect also influenced the other hypothesized paths of affect → knowledge and diabetes social support → affect. The knowledge and diabetes social support measures, despite the change in use of subscales, shows consistent direct effect on self-efficacy. Consistently, diabetes social support, affect, or knowledge did not show any significant direct effect on self-management. Self-efficacy significantly and directly influenced self-management in each of the analyses. Therefore, based on the results in the table below, it seems reasonable to conclude there is stability in the modeling without using specific “missing data” techniques, other than with the variance the modeling the latent affect factor (See Table 37).

Table 37

Comparison of the Direct Effects of the latent factors on Self-efficacy and Self-management used in Sensitivity Modeling (Using Results from Models 10, 12, and 13)

	Effect on Self-efficacy Unstandardized				Effect on Self-management Unstandardized		
Hypothesized Model (No SES)	Direct Effects				Direct Effects		
Time Period	T0 – 564 No SES ^a	T0 - 208* No SES	T0 - 564 FIML* No SES		T0 - 564 No SES	T0 – 208 No SES	T0 - 564 FIML No SES
Latent Constructs							
Diabetes Social Supp	.576**	.469**	.476**		-.340	.024	.027
Affect	-0.160 ^a	(.075)**	(.071)**		(.223)	(.001)	(0.01)
Knowledge	.670**	.239**	.381**		(.048)	(.001)	(.003)
AFFECT ---> KNOWLEDGE	.294*	(.060)*	(.051)*		NA	NA	NA
DSS ----> AFFECT	(0.001)	(1.835)*	(1.11)*		NA	NA	NA
Self-efficacy	N/A	N/A	N/A		.141**	.164**	.188**

a. Diabetes Social Support was using different indicators due to a Heywood case

In reviewing the data from the two sensitivity analyses compared to the similar model using the 564 T0 A1c no SES, there was a significant difference when comparing the fit statistics between Model 8 (564 cov) to Model 10 (208 cov)

(X^2 statistic was 168 df = 50, p value <.001). There was also a significant difference between the X^2 statistic for Model 8 compared to Model 11 (564 FIML Raw data, X^2 statistic was 408, df = 28, p value <.001 (see Table 38).

For example, in reviewing the results from the sensitivity analysis, the estimated fit test statistics of Model were compared to the results of the fit statistics from Model 10 (208 patients who had 100% complete data) and Model 11 (564 raw data FIML). In reviewing the fit indices, both have “less acceptable fit and ranges” for RMSEA (.06 for 564 model and .087 for the 208). The 208 model had a less acceptable SRMR fit (above .07 but below .10) compared to the 564 model. The results of the X^2 difference test between the two models showed that the results are statistically different from Model 8.

It must be noted that the diabetes social support indicator variables were changed due to finding a Heywood case between the initial analysis of the 208 patients and the 564 FIML patient analyses. A review of the sensitivity models with the more detailed estimation results can be made by comparing Figure 19 and Figure 20. The following table is a summary of the fit indices results from the sensitivity analysis using Model 8 as a comparison to Models 10 and 11 (see Table 38).

Table 38

Fit Indices for the Sensitivity Analysis Using Model 10 (A1c -564 cov), 208 100% Complete Model Compared to 564 Model, the 564 Measurement Models, and the 564 Structural Models

Sensitivity Analysis	# Parameters	# of Vars	RM SEA Estimate (PI)	RM SEA L 90% CL	RM SEA U 90% CL	Std RM R (SR MR) (AI)	GFI (AI)	χ^2	χ^2 DF	Pr > χ^2	χ^2 Df Diff	χ^2 Diff Test	Sign/N S
Fit Statistics													
Model 8 = Final A1c No SES (n=564)	37	16	.045	.037	.054	.05	.95	213	99	0			
Model 10 T0 100% NO SES (n=208)	46	20	.09	.076	.097	.08	.83	418	164	0	50	168	P value < .001
MODEL 11 564 Raw FIML NO SES (n=496)	58	20	.07	.061	.075	.14	1	658	86	0	28	408	P value < .001

Chapter 5 - Conclusions and Discussion

Review of the Methodology

This research had three major goals. One goal was to investigate the proposed conceptual model for self-management to gain more insight into the complex relationships between psychosocial factor, specifically self-efficacy and their influence on self-management behaviors and A1c using a proposed conceptual model. Furthermore, this study sought to investigate if self-efficacy was a mediator between self-management and other psychosocial factors. Finally, the study examined whether the original IDEA study's educational intervention influenced knowledge significantly over time based on the proposed conceptual model. Structural equation modeling (SEM) was utilized to allow for complex modeling estimation methods.

It was hypothesized that three latent psychosocial factors, diabetes social support, knowledge, and affect, directly influenced the psychosocial latent factor of self-efficacy and indirectly influenced self-management behaviors and A1c. Self-efficacy was hypothesized to directly influence self-management and act as a mediator between the other psychosocial factors and self-management behaviors.

The original IDEA study utilized an "intent to treat" clinical trial design. Participants were randomized into three groups: one group for individual diabetes education, one received group education, and one group received usual care (no formal education). It was hypothesized that the two groups who received

educational interventions would have a significant increase in knowledge (group education and individual education) when compared to the group who did not receive an educational intervention (usual care).

The methodology involved developing a theory-based conceptual model of how psychosocial factors may influence self-management. After using the five-step SEM method, including theory considerations, the model was respecified. The respecification of the model included: 1) deleting affect directly from influencing SE and diabetes social to support to directly influencing knowledge only and 2) adding a line showing a direct influence from diabetes social support to knowledge.

The respecified theoretical model was then tested using a rich self-report database from the IDEA study of adult patients with type 2 diabetes greater than or equal to 7% A1c using structural equation modeling. Within the five-step SEM process, a two-step estimation method utilizing both a confirmatory factor analysis (CFA) measurement model and full structural regression model was estimated. The respecified model was also compared with two equivalent models and based on chi-squared difference testing, retained as the main study models. Two sensitivity analyses were conducted to explore the impact of missing data: 1) using only the participants who had 100% complete data in both T0 and T4 and 2) using the raw data from the 564 participants rather than covariance data, using direct ML, also known as Full Information Maximum Likelihood (FIML).

Summary of the Results

The following is a summary of the results from the statistical analysis, including the descriptive statistics, correlations, measurement and structural equation modeling analyses, as well as the hypothesis testing.

In relation to the **first research question**, it was found that diabetes social support significantly and directly influenced knowledge ($\beta = .579$, $p \text{ value} \leq .001$) and self-efficacy (β 's range = .482 - .494, $p \text{ value} \leq .001$) and indirectly influenced self-management significantly for diet, exercise, competency and A1c.knowledge (β 's range = .647 - .649, $p \text{ value} \leq .001$). Knowledge directly and significantly influenced self-efficacy and indirectly influenced self-management significantly for the three self-management behaviors (diet, exercise and competency) and A1c (β 's range = .032 - .253, $p \text{ value} \leq .05$ and $p \text{ value} \leq .001$). Affect directly influenced knowledge (β 's range = .296 - .297, $p \text{ value} \leq .05$) and did not directly influence diabetes social support or self-efficacy. Affect indirectly through knowledge significantly influenced SE (β 's range = .192 - .194, $p \text{ value} \leq .05$) and self-management (β 's range = .035 - .075, $p \text{ value} \leq .05$) in adults with type 2 diabetes for exercise and A1c only.

The most important finding pertains to the **second research question**. This question examined the mediation role of self-efficacy with self-management. It was determined that self-efficacy did partially mediate self-management (Sobel test was significant at 2.41, $p \text{ value of} < .05$), specifically, for knowledge. SE did not mediate diabetes social support (although there was a significant direct influence on

SE) or affect (no significant influence to SE). Results showed that diabetes social support, knowledge, and affect had no direct influence on SM, but indirectly influenced SM (with the exception of affect for diet and competency). Interestingly, during respecification, it was discovered that knowledge also served as a mediator for DSS and was directly influenced by affect (Sobel test was significant at 2.454, p value of $< .014$).

The **third research question** hypothesized that the study educational intervention (group and individual education) would have significantly increased knowledge in T4 over those who received usual care during the study. Analysis using 2-tailed t-tests did not show any significant increase in those who received educational interventions after T0 (baseline) in T4.

Demographic characteristics of age, gender, ethnicity (white or non-white), education level, employment status, insulin use, duration of diabetes, and marital status were included in the model as exogenous characteristics. There was a significant effect of age on SE for all SM behaviors and A1c and on SM for diet, competency and A1c, but not exercise. Gender was significant with SE on all self-management behaviors and A1c and with SM only for diet, not for exercise, competency or A1c. Race was only significant with SE and SM for the A1c outcome model and with competency for SM. Educational level was only significant with diet in SE and SM. Employment status and duration of diabetes were only significant with SM in the A1c model. Insulin use was significant for all

SM behaviors and A1c but not for SE. Marital status was not significantly related with SE and only significantly related to SM in diet and A1c.

The more parsimonious model which included the exogenous characteristics (Model 7) was retained over a model without SES factors or with knowledge switched before self-efficacy (Models 8 and 9). The X^2 difference test between these models was statistically significant at the .001 level.

Overall, the proportion of explained total variance in Models 4-7 was from 7–23% (r-squared) for SM; with diet and competency at 7%, exercise at 9%, and A1c at 23%. For self-efficacy, the r-squared explained variance ranged from 57–58%. Diabetes social support, knowledge, and affect had consistent r-squared variances across the SM behaviors and A1c at 5.3%, 2% and 13% respectively. Knowledge in the A1c model had an r-squared of 16%.

Discussion of Major Findings

The final T0 models (Models 4-7) estimation results were obtained from the use of JMP 10.0.2 PRO software and were shown in Chapter 4, Figures 12-15 and Tables 16– 19. The mean, standard deviation, and variances of the correlations for the scores of affect, diabetes social support, knowledge, self-efficacy, and self-management were presented in Tables 9-10.

The CFA measurement modeling showed the indicators loaded onto the proposed latent factors for diabetes social support, knowledge, affect, and self-efficacy adequately.

The results obtained from structural regression modeling for diet, exercise, self-care ability, competency, and A1c (Models 4-7) showed a direct and significant influence of affect and diabetes social support on knowledge. Knowledge and diabetes social support showed a direct and significant relationship to self-efficacy. The directions from the path analysis suggest that increased affect (reduced anxiety and depression, positive attitude) and increased diabetes social support increase knowledge and increased diabetes social support and knowledge increased self-efficacy, which in turn predicted self-management behaviors and A1c moving positively.

As predicted, self-efficacy showed a significant direct relationship with the dependent variable, self-management. Diabetes social support had a positive and indirect relationship with self-management, except the A1c Model was negative and not significant. Affect had a positive and indirect relationship with self-management except for diet and competency. The results suggest that self-efficacy mediates knowledge directly to increased self-management. Somewhat surprising, there was no significant direct relationship found between affect and self-efficacy. It was discovered that knowledge is a mediator for diabetes social support.

These results demonstrate there are significant relationships between knowledge, affect, and diabetes social support. It also shows that knowledge and diabetes social support are significantly influencing self-efficacy, and self-efficacy is significantly influencing self-management. The following sections will review

the results in more detail compared with the literature and the hypothesized conceptual model.

Knowledge and self-efficacy. The study results show a significant relationship between knowledge and self-efficacy. SE appears to be a mediator to self-management for knowledge. Knowledge was shown to have a significant association directly with self-management, but research has not shown it as a mediator to self-management (Abourizk et al., 1994; Beeney et al., 2003; Lorig, Sobel, Bandura, & Holman, 1993; Lori, Seleznick et al., 1989; Peyrot, 1985). This indicates there may be a mediator between knowledge and self-management. Based on health behavior theory, in particular social cognitive theory (SCT) and self-determination theory (SDT), there is evidence that with an increased sense of self-determination (perceived self-efficacy), increased self-management behaviors and outcomes are attained (Williams et al., 2009). Again, SDT predicts that people with perceived competence, or knowledge, for managing their diabetes with respect to critical self-management behaviors were more effective in managing their diabetes (Williams et al., 2004).

These results align with recent literature establishing that knowledge, measured by patients having attended a diabetes education class, was the most significant predictor of successful diabetes self-management (Critchley et al., 2012; Holly, 2012). This research validates recent literature establishing health literacy as having an indirect effect on diabetes self-management and an indirect effect on glycemic control through a direct effect on social support (Osborn, et al., 2010). It

adds to our understanding, as SE was a significant mediator between knowledge and self-management. Diabetes knowledge, similar to research in 2003, was in this study significantly related to demographic measures including gender, ethnicity, education level, and insulin use (Gazmararian et al., 2003).

The mediation of knowledge by diabetes social support was discovered in the respecification process. This significance has implications for the important role diabetes social support plays in facilitating learning.

Diabetes social support and self-efficacy. Unlike most current research findings, there was a significant and direct relationship between diabetes social support (DSS) and self-efficacy (SE) found in this research. There is also evidence of DSS being mediated by knowledge. There was no evidence that DSS, directly or indirectly, was associated with affect. DSS directly and indirectly through knowledge was shown to positively influence self-efficacy and self-management behaviors, but not A1c outcomes.

It is widely recognized that social support contributes to improved chronic disease management (Kronish & Mann, 2010). These results align with the growing evidence that self-efficacy is one of the psychosocial mediators through which social support operates (Cutrona & Troutman, 1986; Duncan & McAuley, 1993; Gulliver et al., 1995; McFarlane et al., 1995). Despite our understanding of the importance of social support in managing a chronic disease, recent chronic disease models such as the patient activation measure (PAM) developed by Hibbard (1997) did not find significance in diabetes social support as a predictor of patient

activation levels; thus it is not currently included in the patient activation measure. This study does show diabetes social support as an important component in the model for self-management behaviors through a direct link with both knowledge and self-efficacy. The study results are similar to those reported by Nakahara et al. (2006) and Nozaki et al. (2009), where social support was indirectly related to self-management through self-efficacy. Other research in diabetes self-management supports this conclusion and has shown that the odds of improved self-management are 2.35 times higher among patients with greater levels of social support (DiMatteo, 2004).

Affect and self-efficacy. The above results do not support a significant relationship between affect and self-efficacy but do show that affect indirectly and significantly influences self-management. There continues to be a lack of clear understanding of how depression or anxiety and stress are associated with glycemic control (A1c). This study does show increased understanding of these complex relationships by demonstrating the fact that affect may not be directly linked to self-efficacy but is directly linked to knowledge and indirectly influences self-efficacy and self-management. These results used a latent affect variable (including depression), yet did not show alignment with the studies that have shown a direct link between depression and self-management (Chiu et al., 2010; Egede & Osborn, 2010; Nozaki et al., 2009).

Recently the literature has presented research showing that diabetes-related distress, distinct from depression, may be more clinically prevalent than depression

(Fisher, et al., 2007). Diabetes-related distress has shown evidence of being mediated by self-efficacy, so it was surprising that this was not a result of this analysis (Nakahara et al., 2006; Nozaki et al., 2009).

Positive and negative attitudes have been associated with self-management behavior performance (Anderson et al., 1993; Fitzgerald et al., 1996; Michigan Diabetes Research & Training Center, 2008; Peyro & Rubin, 1997). There was some concern that outliers in the affect data measures and measurement error may be contributing to instability in the latent factor “affect” in this SEM modeling. In addition, because the attitude was scaled from a negative to a positive, it was difficult to find a way to synchronize the directionality of this measure with the other affect measures: depression and distress. The DCP attitude measure was an unstable measure in the structural model despite its having a significantly high loading factor.

All of the affect measures loaded high onto affect in the measurement model phase. The latent affect factor showed significance to self-efficacy in the measurement phase of the SEM modeling when diabetes social support was measured using the composite scores of diabetes support needs, diabetes support received, and diabetes attitude from the DCP. The DSS measures were changed to using a dummy variable of the six social support subscales from the DCP due to a Heywood case. The DSS measured the difference between the participant’s definition of needs and what was met of those needs by their social support. With

these new measures, diabetes social support became not only significant directly to knowledge but also significant to self-efficacy.

Due to the high correlations between the measures in the affect latent factor, it is possible that multicollinearity among the observed variables will be the issue. When trying to control for high correlation by constraining error variances, there was no difference in model outcomes. Therefore, further modeling with error correlations or correcting for any undiscovered multicollinearity of these observed indicators may elicit a more stable latent factor. There is consistent literature showing the significance of effect on self-management.

Self-efficacy and Self-management Behaviors and A1c. There was a significant and direct relationship between self-efficacy and self-management behaviors and A1c as predicted in the conceptual model. The results are similar to research showing higher self-efficacy encourages setting higher goals and feeling more committed to those goals, thus increasing self-management behaviors (Bandura & Wood, 1989). Accessible values and goals are the substructures of meaning that an individual gives to his or her own life. Thus, an individual with high self-efficacy will render more efforts to establish self-management behaviors (Bandura, 2004).

Summary of Model Fit Statistic Results: The conceptual model fit test statistics were $\chi^2_{A1c} = 379$ (df = 112; n=564, p-value = .000). The RSMEA estimate was .043 (.037-.051 CI), SRMR was .045, and GFI was .94. The direct effects for knowledge ($\beta = .647^{**}$) influenced SE and SE indirectly influenced A1c ($\beta = .253$,

p value $\leq .001$). DSS directly influenced knowledge ($\beta = .579$, p value $\leq .001$) and SE (β 's range = .482, p value $\leq .001$). Affect directly influenced knowledge (β 's range = .296, p value $\leq .05$) and indirectly influenced SE (β 's = .192, p value $\leq .05$). A second hypothesis found SE mediated SM and A1c only for knowledge, not for DSS or affect. DSS, knowledge, and affect indirectly influenced SM behaviors and A1c significantly (affect only for exercise and A1c). Knowledge was a mediator for DSS to SE.

The respecified proposed conceptual model has merit as it shows the relationship among several important psychosocial factors and their influence on self-management behaviors and A1c and is worth further research.

Study Limitations

This study has several limitations regarding sampling, response rates beyond baseline, missing data, measurement error, and complex model design. A limitation in this study was the use of a secondary data source and sampling response size. Participation bias may have occurred by those who chose to participate in the study compared to those who did not enter the study. Study participants all had some form of insurance, a primary care provider, and had high baseline A1c's to participate, so generalizability of the results is more limited. The original design of the study predicted a 15% response rate and actually achieved an 11% response rate. Although there is very little missing data for T0 (baseline) for this study, for future studies using other time periods, a statistical limitation may be the handling of missing data and ensuring enough power for detecting effects from the psychosocial

factor latent measures. FIML or multiple imputations may resolve some of the instability within the measures that were less stable, as they corresponded to those measures with higher missing data levels. Ideally, the use of SEM with two sensitivity analyses using direct ML and 100% complete patients SEM econometric techniques were able to overcome these limitations.

The impact of the original study's randomized design for education was considered carefully, as interventions were not received by all subjects. Intra-participant relationships to cluster measures are of significant consideration. Studies have shown significant correlations exist among many of the variables under study, which makes analysis difficult. For example, baseline A1c has significant predictive ability with follow-up A1c; it was more difficult to measure true effects of the other variables of interest in this research. As correlation increases, it was more difficult to argue that the variables have independent effects. Causal and counterfactual relationships exist among the variables of interest and must be noted as limitations.

Measurement limitations exist in use of multiple survey tools that do not all have similar construct, convergent, or content validity. Even with validated measurement tools, the predictive validity of each survey instrument may be limited, as each item of the survey question must refer to something that is directly observable by the patient (Klein, 2011). With multiple measurement tools, one must be confident that the measurement models are ensuring that the theoretical variables are the same in different samples. For example, the DES measure of perceived self-efficacy is not necessarily translated across ethnic races, and consideration of this

will be required in future study designs. Another measurement limitation exists with observed measures contributing at different ranges to the latent constructs designed in the modeling.

Limitations and Assumptions Regarding SEM. Limitations exist when attempting to use structural equation modeling (SEM) to make inferences in a complex model as proposed. Hypothesized causal effects in observational studies can only be substantiated from a combination of data and untested theoretical assumptions, not from the data alone (Pearl, 2011). With the use of structural equation modeling, assuming the conceptual model is true may lead to erroneous inferences as was initially experienced, creating the need for model respecification. Using only cross-sectional data precludes making any causal inferences. Even when success was claimed when testing the fit of the model, it still must be noted that the model test statistic chi-squared was significant, and therefore only with the assumption of large sample size was the next step in SEM fit testing able to continue. Conservatively, it could put the entire results into question. It must also be noted that the proposed conceptual model is one of many viable models that may exist as noted when testing for equivalent models and using goodness of fit measures.

The sample size is important in SEM modeling; a larger sample is always desirable. Due to the complexity of this proposed model, despite it being larger than most SEM literature, the sampling ratio was on the lower end required. Variable selection, scaling, and transformations of covariates were made as required. The

consistency of the results from the model testing approaches for the sensitivity analyses did allow one to concur with the unknown assumption of MAR missing data.

Research Implications

The aim of this research proposal is highly relevant to the debate on increasing patient-centered care approaches, improving self-management behaviors, improving diabetes outcomes, and reducing health-care costs for chronic disease patients with diabetes. As chronic disease patients account for approximately 60% of all health-care expenditures, this is important work. In addition, there are currently over 26 million patients with type 2 diabetes and over 50 million pre-diabetics (ADA, 2012).

The results of this research will be of interest to health systems working on care management and chronic disease management within accountable care organizations. Ambulatory clinics and physicians; ancillary health providers; diabetes educators; health-care quality, research, and health associations; insurers; including Medicare and Medicaid; patient advocacy groups; and patients who are invested in improving the quality and efficacy of diabetic care, reducing chronic disease prevalence, and reducing the cost curves may be interested as well. Organizations such as the Minnesota Community Measurement project may find these outcomes of interest in determining what information to measure and collect related to diabetes from health-care providers across the state.

The current findings build on other literature showing that self-efficacy relates significantly to improved glycemic control (A1c) (an outcome) and self-management behaviors (Brody, Kogan, Murry, Chen, & Brown, 2008; Daly et al., 2009; Inzucchi et al., 2012; Maddigan, Majumdar, & Johnson, 2005; Sacco et al., 2007; Williams, Freedman, Zeldman, & Deci, 2004). Together, these studies suggest that clinicians who focus on developing increased patient self-management through understanding their diabetes care and knowledge, increasing diabetes social support, and understanding their emotions can actually help patients build diabetes self-efficacy and thus improve self-management behaviors and glycemic control. Similar to other studies with multiple psychosocial factors being examined, self-efficacy again emerged as a powerful predictor of self-management behavior (Bandura, 1977, 1997; Gonder-Frederick, 2002; McCaul, Glasgow, & Shafer, 1987; Mirowsky & Ross, 2010).

On a practical level, the results of this study suggest that health-care professionals, including administrators, diabetes nurse educators, physicians, and nurse practitioners may facilitate increased self-management, if they elicit and improve patient self-efficacy. The standardized direct results from SE to SM (exercise) were at the .29** level and suggest that a level increase of self-efficacy one full standard deviation above the mean predicts a self-management level just over .29 standard deviations above the mean. This lends support to the a priori theory that when trying to positively influence and increase self-management behavior performance, self-efficacy may be one of the most important psychosocial

factors to be measured and used to assist patients with improving. This is consistent with literature that shows higher self-efficacy being directly associated with higher self-rated, self-management behavior (McCaul et al., 1987; Padgett, 1991; Williams et al., 2005; Senecal et al., 2000). These results are consistent with the literature which points out that neither knowledge nor social support predicted self-management behavior. Theory points to knowledge as a precondition for behavior change, but on its own is insufficient (Bandura, 1998). Perceived self-efficacy was the only factor that predicted performance of each measured aspect of self-management behavior: diet, SMBG testing, and self-administration of insulin (McAuley, 1992, 1997). In addition, noted in research is the important point that self-efficacy is consistent at different points in the health behavior change process, whether at the initial adoption or the maintenance phase (Bandura, 1977; Renner et al., 2012, Rothman, 2000). Noted in research, people with diabetes know they should exercise but fail to do so. Social Cognitive Theory (SCT) emphasizes the importance of perceived self-efficacy, because it influences the activities in which people choose to engage, the energy they put into these activities, and the persistence they demonstrate in the face of obstacles (Bandura, 1997, 2004).

Using current accessible measurable self-report tools for perceived self-efficacy may be critical to the process of assisting patients with self-management of their chronic disease. This research may assist health clinicians in selecting the best assessment tools, as time and money for survey data collection at a clinic visit are very limited. The practical nature of self-report measurement instruments being

made available to patients on a regular basis during their care is noted here. For example, instruments such as the PHQ -2 and PHQ-9 are important, as they are more commonly used in the screening for patients. As distress has become noted as the more significant emotional measure in diabetes care, the PAID instrument loaded higher (.840) than the PHQ-9 for example, meaning it influenced the latent factor of affect more significantly. The DCP-attitudes section (.856) loaded the highest and could potentially be used for measuring affect alone. Diabetes social support was measured using the DCP sections on social support and loaded high, ranging from .561 to .717. Knowledge's high loading measure was the understanding of care section from the DCP (.751) and health literacy showing very low impact on knowledge. This may be due to measurement instruments not be updated for current health literacy issues. For measuring self-efficacy, both the DCP - care ability and DCP - self-care management sections were used and loaded similar at .869 and .840 respectively, compared to the DES measure loading at .550. Overall, it appears for patients with type 2 diabetes that the DCP instrument sections may have a more comprehensive measurement to assist patients and clinicians in improving self-management outcomes.

As in the literature, self-efficacy appears to consistently act as the mediator variable influencing individual self-management behaviors and resulting outcomes (Annesi, 2011). Finally, this research supports the consideration of pulling together the research and literature findings from three disciplines: health behavior theory, psychology, and chronic disease management. It supports more understanding of

why continued research focused on social cognitive theory (Bandura, 1986) and chronic disease self-management (CDSMP) (Holman and Lorig, 1992; Lorig, 2003, 2005) methods may be producing more efficacious results in improving self-management in patients with type 2 diabetes, as they are based on theory using self-efficacy as an important component.

Suggestions for Future Research

Several study directions may be important to continue with this research. Self-management behavior as the dependent variable was studied, with A1c included, even though it is an outcome. Specifically, based on extensive literature showing that self-management behaviors are a mediator to outcomes, the current conceptual model could be enhanced to add an “outcomes” section to the right of self-management behaviors (A1c would move to that section). This would allow for the additional testing of self-management behavior as a mediator to outcomes. Current theory and literature justifies self-management behavior as a step in leading to outcomes (both quality of life and clinical measures such as A1c). Most literature is focused on the A1c impacts of psychosocial factors, and it seems important to have richer information, including QOL, to ensure patient involvement in self-management behaviors. The IDEA database has not only rich clinical outcomes data (hyperglycemia, bmi, blood pressure) available but also includes self-reported quality of life (QOL) data.

Current research is finding interesting implications regarding self-efficacy and self-management using longitudinal latent change modeling to evaluate

multiple psychosocial factors and models that are more complex. The IDEA database is well designed as it has twelve-month panel data, to accomplish this research using SEM. The assessment of variables at different times provides a measurement framework consistent with the specification of directional effects. To infer presumed causal effects in SEM, five basic conditions must be met (Mulaik, 2009; Pearl, 2000), including;

- Temporal precedence—the presumed cause (X) must occur before the presumed effect (Y).
- Association—there is an observed covariance or variation in the cause related to the presumed effect.
- Isolation—there are no other plausible explanations.
- Correct effect priority—the direction of the causal relation is correctly specified.
- Distribution form—the known distribution forms of the parameters using probabilistic causality assumptions are specified and reasonable (Klein, 2011).

In particular, it would be interest to determine if there is longitudinal effect differences using the psychosocial factors at T0, with T2 self-efficacy and T4 self-management behaviors and A1c. This modeling has found significant results in work recently led by Hankonen et al., 2010.

Doing comparison work on SEM missing data using direct ML (FIML) and multiple imputation as sensitivity analyses is of current interest in the SEM research

world. There is continued debate about the efficiency of direct ML versus multiple imputations, which would be of interest in latent SEM modeling.

There are many variables available in the IDEA database that were not used in this study and may contribute to further, more effective testing of this conceptual model. Finally, it would be of interest to determine if these findings and conceptual model may be further applicable to other high self-management requirement chronic disease types such as congestive heart failure and chronic obstructive pulmonary disease.

Conclusions

In this study, diabetes social support and knowledge emerged as direct influences upon self-efficacy. Affect is directly influencing knowledge and indirectly influencing self-efficacy and self-management. Self-efficacy is directly influencing self-management. Knowledge appeared to be the most potent factor among the psychosocial factors of affect, diabetes social support, and knowledge. Direct links were not found between either affect to self-efficacy or diabetes social support to affect as predicted. In an equivalent model, it was shown that several exogenous characteristics significantly influence the model and are appropriate to include. The other equivalent model demonstrated that self-efficacy is in the correct order in the model, as studying it as a precedent to knowledge did not show any significance, and the significant direct and indirect relationship to self-management remained. In addition, the significant relationship between diabetes social support

and affect to knowledge became insignificant. Again, the respecified model was retained as the more parsimonious model.

This research uncovered intriguing findings and has identified future research areas needing more attention regarding knowledge and its role as a mediator to diabetes social support and its importance to self-efficacy. In addition, much of the literature does not show diabetes social support as having a significant impact on self-efficacy or self-management, yet this relationship was found to be directly significant to knowledge and indirectly influencing self-efficacy and self-management behaviors and A1c. Self-efficacy continues to be the significant factor of interest in the complex modeling of psychosocial factors that assist in predicting self-management behavior performance. Future research could build upon this study by continuing to refine the conceptual model drawn from three aspects of literature and potentially studying this in relation to more aspects of the comprehensive biopsychosocial model.

In this study, as in other causal modeling with nontemporal data sets, the paths between the variables cannot be seen as truly causal. A longitudinal study, or modeling of variables over time, is needed to confirm the hypothesized order and conceptual model. As noted above, there are a number of future research efforts possible from this research.

The proposed conceptual model for an integrated patient-centered self-management behavior model has shown some merit. The value of the model may come from using related elements pulled from three existing theoretical models: the

biopsychosocial conceptual framework (Engel, 1977; Schwartz, & Weiss, 1978; Anderson, 1998; Kaplan, 1990), evidence-based health behavior theories, primarily social cognitive theory (Bandura, 1977, 1986; DePalma, 2011; Nozaki, 2009; Sacco, 2007; Tierney et al., 2011; Yi et al., 2008), and two biomedical chronic disease self-management models (Bodenheimer, Wagner, & Grumbach, 2002; Hibbard, 2004; Lorig, 1999). The current study's analysis of the confluence of these theoretical models was rooted in their shared emphasis on the importance of understanding the impact psychosocial factors have on self-management, and all identified *self-efficacy* as a central component in self-management behavior change, especially in a chronic disease situation. Health behaviors research of adults with type 2 diabetes, especially social cognitive theory (SCT), has provided evidence that individuals with improved affect, increased knowledge, more positive social support, and higher self-efficacy tend to have better self-management behaviors and clinical outcomes (Bandura, 1998; Bandura, 2004; Chiu et al., 2010; Critchley, Hardie, & Moore, 2012; Tierney et al., 2011).

In summary, the current research has demonstrated that increasing affect (reducing depression and anxiety) and diabetes social support influence increasing knowledge, thus directly increasing self-efficacy. Increasing self-efficacy has been shown to have a significant and direct influence on increased self-management behaviors and reduced A1c levels. The literature shows that increased self-management behaviors and better glycemic control leads to improved outcomes.

Health-care systems and providers have identified the need to assist the 26 million adult patients currently with type 2 diabetes in better self-management, and further, to prevent the onset in the 57 million Americans who have the potential to become diabetic. Improved self-management behaviors, thus improved outcomes in patients with type 2 diabetes, saves lives, increases quality of life, and reduces costs.

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Appendices

Appendix A: CFA Analysis Results for Latent Factors of Diabetes Social Support, Affect, Knowledge, Self-efficacy, and Self-management

TO CFA – Principal Components Analysis

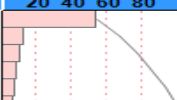
T0 Diabetes Social Support:

Principal Components: on Correlations

Correlations

	t0_met_meals	t0_met_meds	t0_feet_met	t0_exercise_met	t0_SMBG_met	t0_feelings_met
t0_met_meals	1.0000	0.3560	0.3770	0.4677	0.3546	0.3894
t0_met_meds	0.3560	1.0000	0.5687	0.4418	0.5423	0.4460
t0_feet_met	0.3770	0.5687	1.0000	0.4527	0.4882	0.4030
t0_exercise_met	0.4677	0.4418	0.4527	1.0000	0.4391	0.4912
t0_SMBG_met	0.3546	0.5423	0.4882	0.4391	1.0000	0.5220
t0_feelings_met	0.3894	0.4460	0.4030	0.4912	0.5220	1.0000

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	3.2542	54.236					54.236
2	0.7540	12.567					66.803
3	0.6284	10.473					77.276
4	0.5109	8.516					85.791
5	0.4356	7.260					93.051
6	0.4169	6.949					100.000

Loading Matrix

	Prin1	Prin2	Prin3	Prin4	Prin5	Prin6
t0_met_meals	0.64873	0.61270	0.26782	0.36241	0.01367	-0.02213
t0_met_meds	0.76729	-0.35791	0.18911	0.04560	-0.04078	-0.49361
t0_feet_met	0.74910	-0.27218	0.40172	-0.12800	0.28117	0.32856
t0_exercise_met	0.74504	0.31257	-0.04037	-0.53282	-0.24826	-0.00773
t0_SMBG_met	0.76471	-0.27051	-0.24501	0.27757	-0.37791	0.24928
t0_feelings_met	0.73725	0.07463	-0.54572	0.01423	0.38759	-0.05140

T0 Knowledge:

Principal Components: on Correlations

	t0_ump_dcp_score	t0_imp_care_dcp_score	t0_literacy_by_100
t0_ump_dcp_score	1.0000	0.2160	0.1561
t0_imp_care_dcp_score	0.2160	1.0000	0.1360
t0_literacy_by_100	0.1561	0.1360	1.0000

Covariance Matrix

	t0_ump_dcp_score	t0_imp_care_dcp_score	t0_literacy_by_100
t0_ump_dcp_score	0.63338	0.11377	0.00409
t0_imp_care_dcp_score	0.11377	0.43798	0.00296
t0_literacy_by_100	0.00409	0.00296	0.00108

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	1.3412	44.707					44.707
2	0.8765	29.217					73.923
3	0.7823	26.077					100.000

Loading Matrix

	Prin1	Prin2	Prin3
t0_ump_dcp_score	0.71107	-0.25517	-0.65518
t0_imp_care_dcp_score	0.68946	-0.42718	0.58495
t0_literacy_by_100	0.60018	0.79304	0.10428

Principal Components: on Correlations

Correlations

	t0_ump_dcp_score	t0_imp_care_dcp_score
t0_ump_dcp_score	1.0000	0.2160
t0_imp_care_dcp_score	0.2160	1.0000

Covariance Matrix

	t0_ump_dcp_score	t0_imp_care_dcp_score
t0_ump_dcp_score	0.63338	0.11377
t0_imp_care_dcp_score	0.11377	0.43798

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	1.2160	60.801					60.801
2	0.7840	39.199					100.000

Loading Matrix

	Prin1	Prin2
t0_ump_dcp_score	0.77975	0.62609
t0_imp_care_dcp_score	0.77975	-0.62609

T0 Affect:

Principal Components: on Correlations

Correlations

	t0_phq2_score	t0_phq9_sc_by10	t0_paid_scor_by100	t0_att_+20
t0_phq2_score	1.0000	0.8704	0.4876	0.5337
t0_phq9_sc_by10	0.8704	1.0000	0.5951	0.5846
t0_paid_scor_by100	0.4876	0.5951	1.0000	0.7154
t0_att_+20	0.5337	0.5846	0.7154	1.0000

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	2.8972	72.431					72.431
2	0.6962	17.406					89.836
3	0.2884	7.210					97.046
4	0.1182	2.954					100.000

Loading Matrix

	Prin1	Prin2	Prin3	Prin4
t0_phq2_score	0.85643	-0.46178	0.04557	0.22629
t0_phq9_sc_by10	0.90330	-0.33995	-0.07370	-0.25109
t0_paid_scor_by100	0.81514	0.44961	-0.36033	0.05963
t0_att_+20	0.82663	0.40654	0.38864	-0.01887

Principal Components: on Correlations

Correlations

	t0_phq2_log1	t0_phq9_log1	t0_paid_scor_by100
t0_phq2_log1	1.0000	0.8002	0.4851
t0_phq9_log1	0.8002	1.0000	0.5791
t0_paid_scor_by100	0.4851	0.5791	1.0000

Covariance Matrix

	t0_phq2_log1	t0_phq9_log1	t0_paid_scor_by100
t0_phq2_log1	0.36227	0.18271	0.06150
t0_phq9_log1	0.18271	0.14391	0.04627
t0_paid_scor_by100	0.06150	0.04627	0.04436

Loading Matrix

	Prin1	Prin2	Prin3
t0_phq2_log1	0.89162	-0.35280	0.28381
t0_phq9_log1	0.92704	-0.18686	-0.32510
t0_paid_scor_by100	0.77370	0.63046	0.06246

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	2.2530	75.100					75.100
2	0.5569	18.562					93.662
3	0.1901	6.338					100.000

Principal Components: on Correlations

Correlations

	t0_phq2_score	t0_phq9_sc_by10	t0_paid_scor_by100	t0_att_20by100
t0_phq2_score	1.0000	0.8704	0.4876	0.5337
t0_phq9_sc_by10	0.8704	1.0000	0.5951	0.5846
t0_paid_scor_by100	0.4876	0.5951	1.0000	0.7154
t0_att_20by100	0.5337	0.5846	0.7154	1.0000

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	2.8972	72.431					72.431
2	0.6962	17.406					89.836
3	0.2884	7.210					97.046
4	0.1182	2.954					100.000

Loading Matrix

	Prin1	Prin2	Prin3	Prin4
t0_phq2_score	0.85643	-0.46178	0.04557	0.22629
t0_phq9_sc_by10	0.90330	-0.33995	-0.07370	-0.25109
t0_paid_scor_by100	0.81514	0.44961	-0.36033	0.05963
t0_att_20by100	0.82663	0.40654	0.38864	-0.01887

T0 Self-efficacy: (Raw data)

Principal Components: on Correlations

Correlations

	t0_des_score	t0_care_abil_dcp_score	t0_self_care_dcp_score
t0_des_score	1.0000	0.4818	0.4282
t0_care_abil_dcp_score	0.4818	1.0000	0.7366
t0_self_care_dcp_score	0.4282	0.7366	1.0000

Covariance Matrix

	t0_des_score	t0_care_abil_dcp_score	t0_self_care_dcp_score
t0_des_score	0.28234	0.22169	0.16741
t0_care_abil_dcp_score	0.22169	0.74973	0.46931
t0_self_care_dcp_score	0.16741	0.46931	0.54149

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	2.1099	70.330					70.330
2	0.6298	20.994					91.323
3	0.2603	8.677					100.000

Loading Matrix

	Prin1	Prin2	Prin3
t0_des_score	0.72889	0.68334	0.04200
t0_care_abil_dcp_score	0.89896	-0.23087	-0.37225
t0_self_care_dcp_score	0.87777	-0.33099	0.34636

Principal Components: on Correlations

Correlations

	t0_des_score	t0_care_abil_dcp_score
t0_des_score	1.0000	0.4819
t0_care_abil_dcp_score	0.4819	1.0000

Covariance Matrix

	t0_des_score	t0_care_abil_dcp_score
t0_des_score	0.28234	0.22161
t0_care_abil_dcp_score	0.22161	0.74906

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	1.4819	74.094					74.094
2	0.5181	25.906					100.000

Loading Matrix

	Prin1	Prin2
t0_des_score	0.86078	0.50898
t0_care_abil_dcp_score	0.86078	-0.50898

T4 CFA

T4 DIABETES SOCIAL SUPPORT CFA:

Principal Components: on Correlations

Correlations

	t4_meals_met	t4_meds_met	t4_feet_met	t4_exercise_met	t4_smbg_met	t4_feelings_met
t4_meals_met	1.0000	0.4579	0.4800	0.5103	0.4560	0.5087
t4_meds_met	0.4579	1.0000	0.5861	0.4467	0.5515	0.4640
t4_feet_met	0.4800	0.5861	1.0000	0.4673	0.5887	0.5435
t4_exercise_met	0.5103	0.4467	0.4673	1.0000	0.5387	0.5500
t4_smbg_met	0.4560	0.5515	0.5887	0.5387	1.0000	0.6022
t4_feelings_met	0.5087	0.4640	0.5435	0.5500	0.6022	1.0000

Covariance Matrix

	t4_meals_met	t4_meds_met	t4_feet_met	t4_exercise_met	t4_smbg_met	t4_feelings_met
t4_meals_met	0.17576	0.06374	0.07538	0.09066	0.06779	0.08184
t4_meds_met	0.06374	0.11023	0.07290	0.06285	0.06492	0.05912
t4_feet_met	0.07538	0.07290	0.14032	0.07418	0.07819	0.07813
t4_exercise_met	0.09066	0.06285	0.07418	0.17959	0.08095	0.08945
t4_smbg_met	0.06779	0.06492	0.07819	0.08095	0.12573	0.08195
t4_feelings_met	0.08184	0.05912	0.07813	0.08945	0.08195	0.14727

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	3.5882	59.803					59.803
2	0.6432	10.721					70.523
3	0.5493	9.155					79.678
4	0.4627	7.711					87.390
5	0.3903	6.504					93.894
6	0.3664	6.106					100.000

Loading Matrix

	Prin1	Prin2	Prin3	Prin4	Prin5	Prin6
t4_meals_met	0.72851	0.36137	0.53259	-0.17232	0.06309	-0.14612
t4_meds_met	0.75416	-0.44186	0.23824	0.27610	0.25996	0.18822
t4_feet_met	0.79354	-0.33101	0.04475	-0.17647	-0.47671	0.01806
t4_exercise_met	0.75478	0.39682	-0.15748	0.45995	-0.18234	0.05693
t4_smbg_met	0.81144	-0.13480	-0.31285	-0.02769	0.17367	-0.44112
t4_feelings_met	0.79426	0.17943	-0.29017	-0.33659	0.16742	0.33382

T4 KNOWLEDGE CFA:

Principal Components: on Correlations				
Correlations				
	t4_ump_dcp_score	t4_imp_care_dcp_score		
t4_ump_dcp_score	1.0000	0.4152		
t4_imp_care_dcp_score	0.4152	1.0000		
Covariance Matrix				
	t4_ump_dcp_score	t4_imp_care_dcp_score		
t4_ump_dcp_score	0.58020	0.20544		
t4_imp_care_dcp_score	0.20544	0.42199		
Eigenvalues				
Number	Eigenvalue	Percent	20 40 60 80	Cum Percent
1	1.4152	70.759		70.759
2	0.5848	29.241		100.000
Loading Matrix				
	Prin1	Prin2		
t4_ump_dcp_score	0.84118	-0.54075		
t4_imp_care_dcp_score	0.84118	0.54075		

T4 AFFECT CFA:

Principal Components: on Correlations				
Correlations				
	t4_phq2_1_log	t4_paid_1_by100		
t4_phq2_1_log	1.0000	0.5891		
t4_paid_1_by100	0.5891	1.0000		
Eigenvalues				
Number	Eigenvalue	Percent	20 40 60 80	Cum Percent
1	1.5891	79.457		79.457
2	0.4109	20.543		100.000
Loading Matrix				
	Prin1	Prin2		
t4_phq2_1_log	0.89139	-0.45324		
t4_paid_1_by100	0.89139	0.45324		

Principal Components: on Correlations

Correlations

	t4_phq2_score	t4_paid_1_chi	t4_attit_21_10
t4_phq2_score	1.0000	0.4827	0.0459
t4_paid_1_chi	0.4827	1.0000	0.0823
t4_attit_21_10	0.0459	0.0823	1.0000

Covariance Matrix

	t4_phq2_score	t4_paid_1_chi	t4_attit_21_10
t4_phq2_score	2.04462	0.35500	0.05056
t4_paid_1_chi	0.35500	0.26455	0.03259
t4_attit_21_10	0.05056	0.03259	0.59322

Loading Matrix

	Prin1	Prin2	Prin3
t4_phq2_score	0.84776	-0.16341	0.50459
t4_paid_1_chi	0.85586	-0.08761	-0.50972
t4_attit_21_10	0.21901	0.97495	0.03877

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	1.4992	49.972					49.972
2	0.9849	32.830					82.802
3	0.5159	17.198					100.000

T4 Self-efficacy: (Raw data)

Principal Components: on Correlations

Correlations

	t4_des_score	t4_care_abil_dcp_score
t4_des_score	1.0000	0.6040
t4_care_abil_dcp_score	0.6040	1.0000

Covariance Matrix

	t4_des_score	t4_care_abil_dcp_score
t4_des_score	0.33295	0.29159
t4_care_abil_dcp_score	0.29159	0.69987

Eigenvalues

Number	Eigenvalue	Percent	20	40	60	80	Cum Percent
1	1.6040	80.202					80.202
2	0.3960	19.798					100.000

Loading Matrix

	Prin1	Prin2
t4_des_score	0.89556	0.44494
t4_care_abil_dcp_score	0.89556	-0.44494

Principal Components: on Correlations


Correlations

	t4_r2c_overall	t4_des_score	t4_care_abil_dcp_score
t4_r2c_overall	1.0000	0.2721	0.2599
t4_des_score	0.2721	1.0000	0.6041
t4_care_abil_dcp_score	0.2599	0.6041	1.0000

Covariance Matrix

	t4_r2c_overall	t4_des_score	t4_care_abil_dcp_score
t4_r2c_overall	0.24674	0.07798	0.10800
t4_des_score	0.07798	0.33295	0.29165
t4_care_abil_dcp_score	0.10800	0.29165	0.69996

Eigenvalues

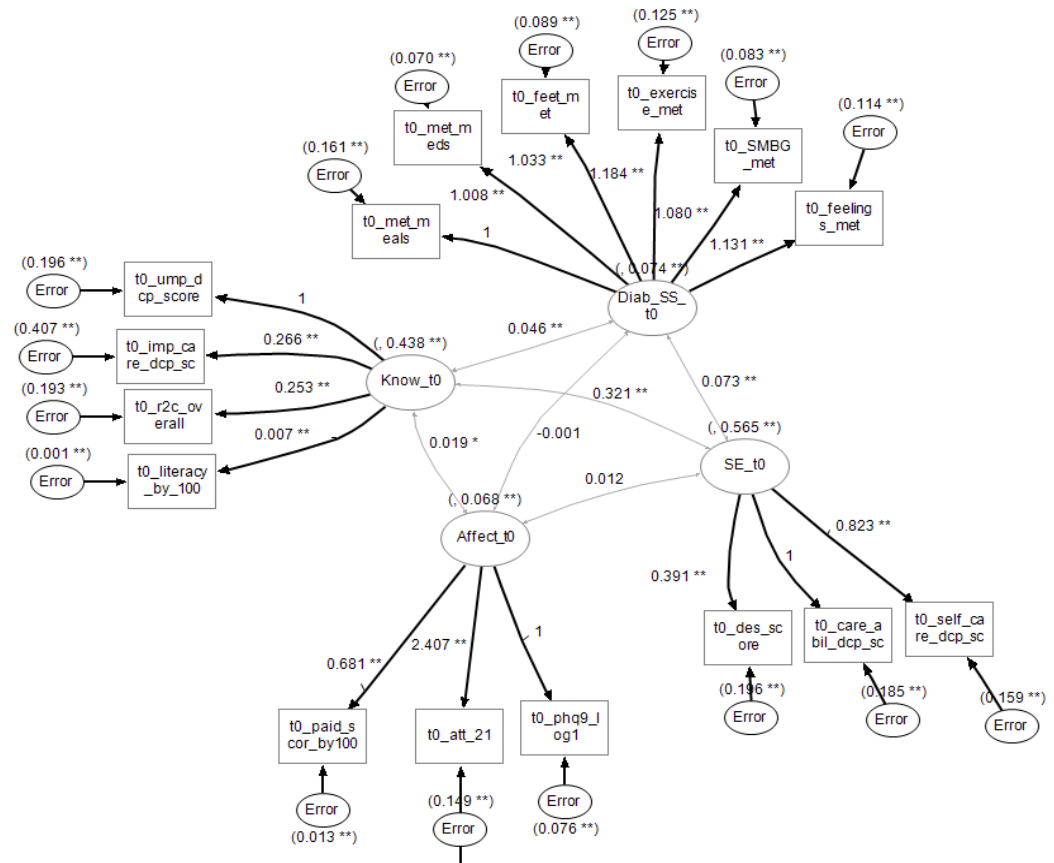
Number	Eigenvalue	Percent	20 40 60 80	Cum Percent
1	1.7845	59.483		59.483
2	0.8198	27.326		86.809
3	0.3957	13.191		100.000

Loading Matrix

	Prin1	Prin2	Prin3
t4_r2c_overall	0.57757	0.81626	0.01114
t4_des_score	0.85427	-0.26505	-0.44719
t4_care_abil_dcp_score	0.84919	-0.28855	0.44229

APPENDIX B:

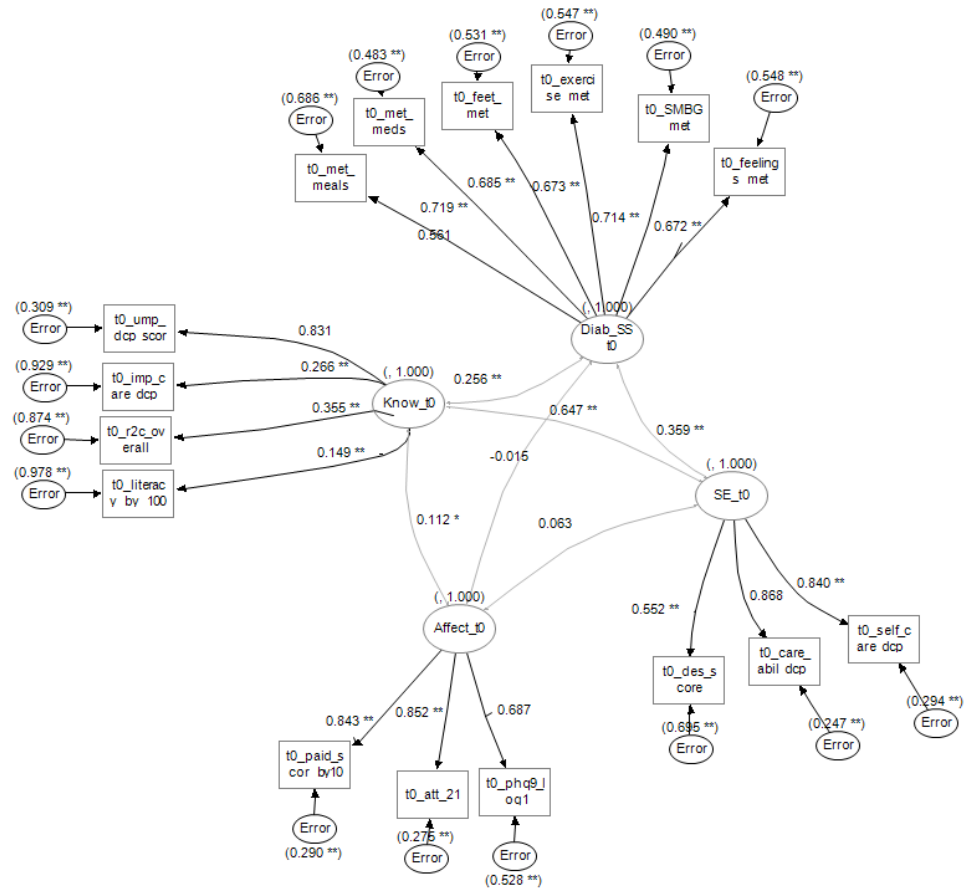
CORR CFA of Affect, Knowledge, Diabetes SS and SE (UNSTD)



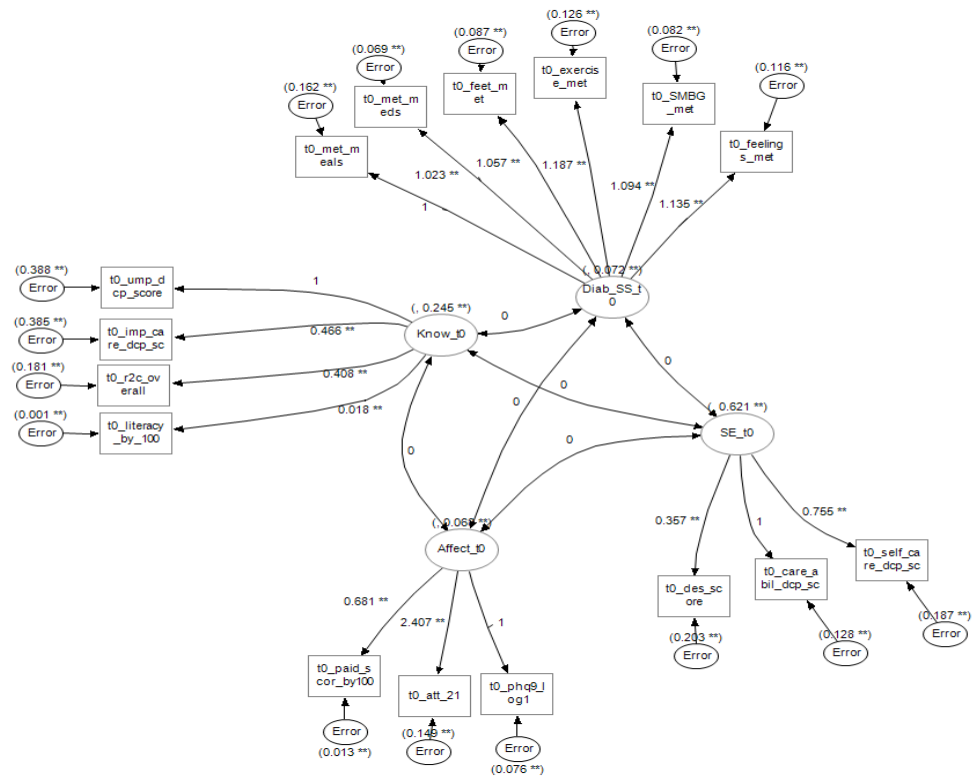
Fit Summary

Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	221.7898
	Chi-Square DF	98
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0457
Parsimony Index	Adjusted GFI (AGFI)	0.9335
	Parsimonious GFI	0.7775
	RMSEA Estimate	0.0474
	RMSEA Lower 90% Confidence Limit	0.0391
	RMSEA Upper 90% Confidence Limit	0.0557
	Probability of Close Fit	0.6889
Incremental Index	Bentler Comparative Fit Index	0.9549

CORR CFA – STD

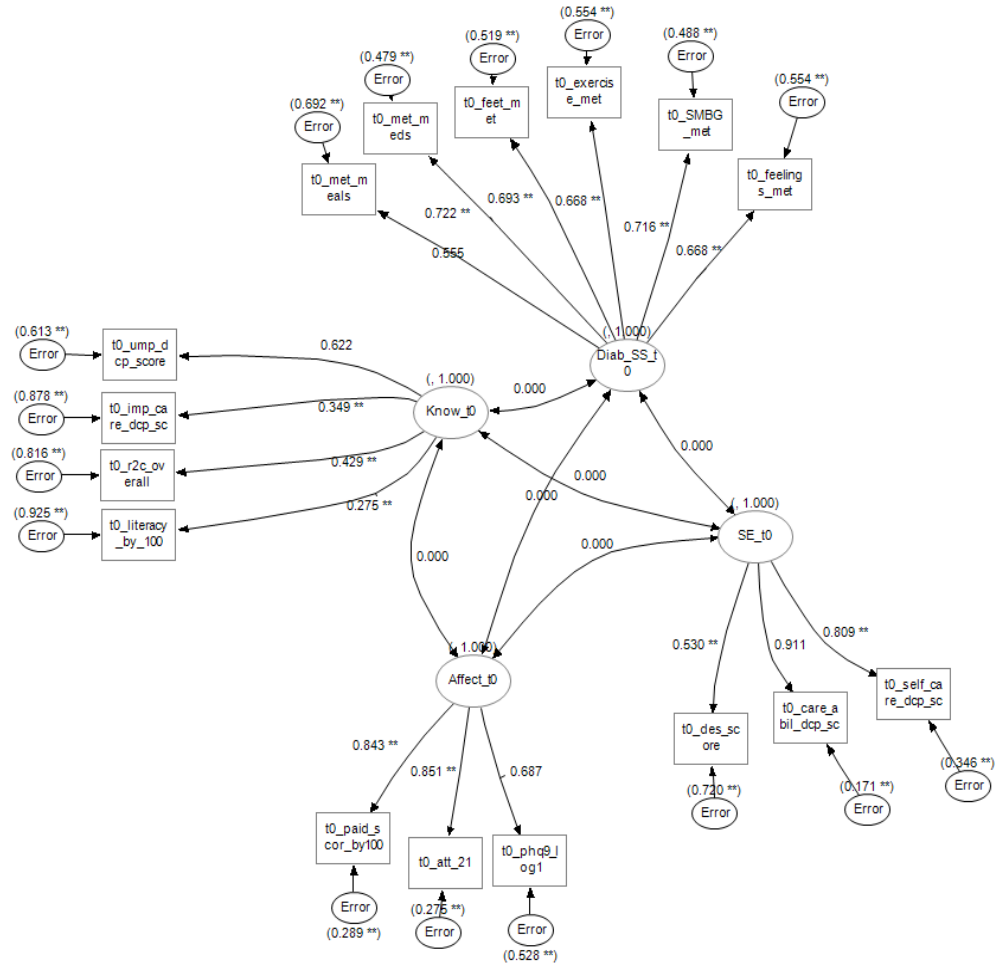


UNCORR CFA – Affect, Knowledge, DSS & SE - UNSTD

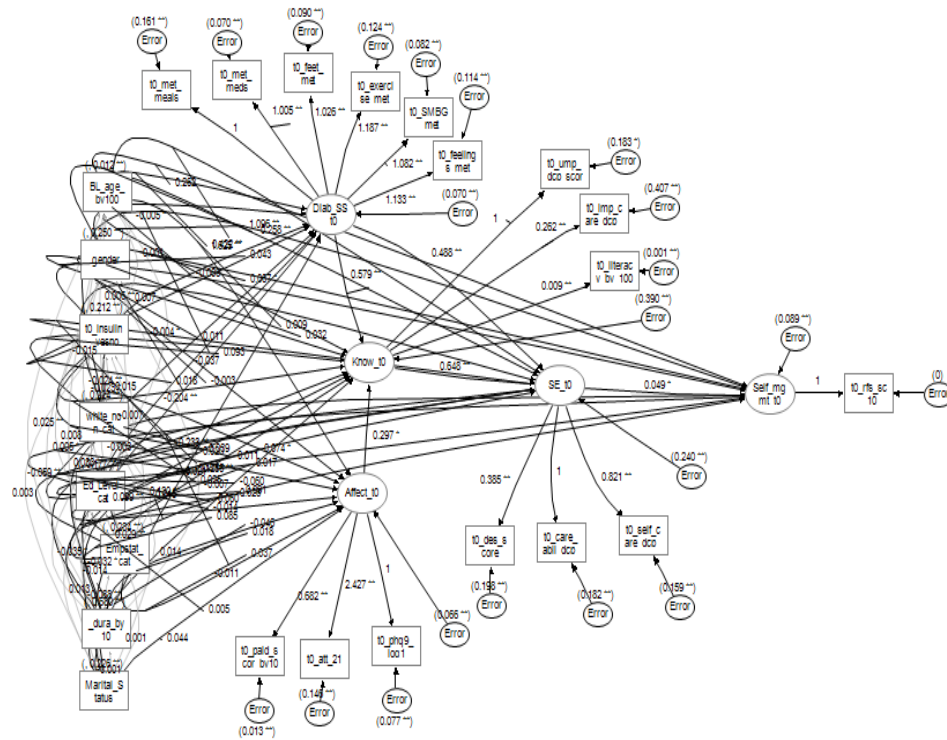


Fit Summary		
Modeling Info	Number of Observations	564
	Chi-Square	438.9365
Absolute Index	Chi-Square DF	104
	Pr > Chi-Square	<.0001
Parsimony Index	Standardized RMR (SRMR)	0.1170
	Adjusted GFI (AGFI)	0.8857
	Parsimonious GFI	0.7909
	RMSEA Estimate	0.0756
	RMSEA Lower 90% Confidence Limit	0.0684
Incremental Index	RMSEA Upper 90% Confidence Limit	0.0830
	Probability of Close Fit	<.0001
	Bentler Comparative Fit Index	0.8779

UNCORR CFA – Affect, Knowledge, DSS & SE – STD



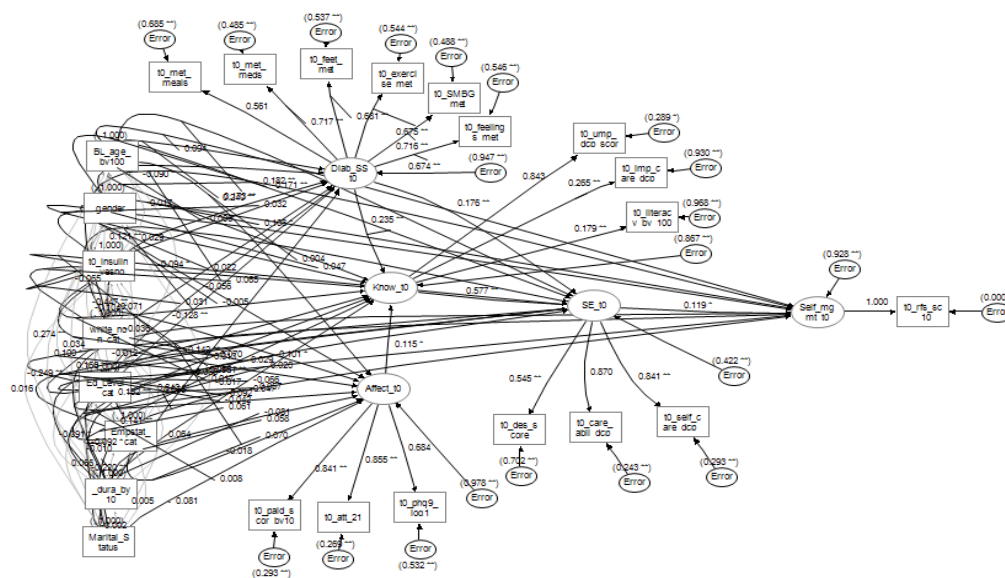
TO FINAL RESPECIFIED –DIET (UNSTD)



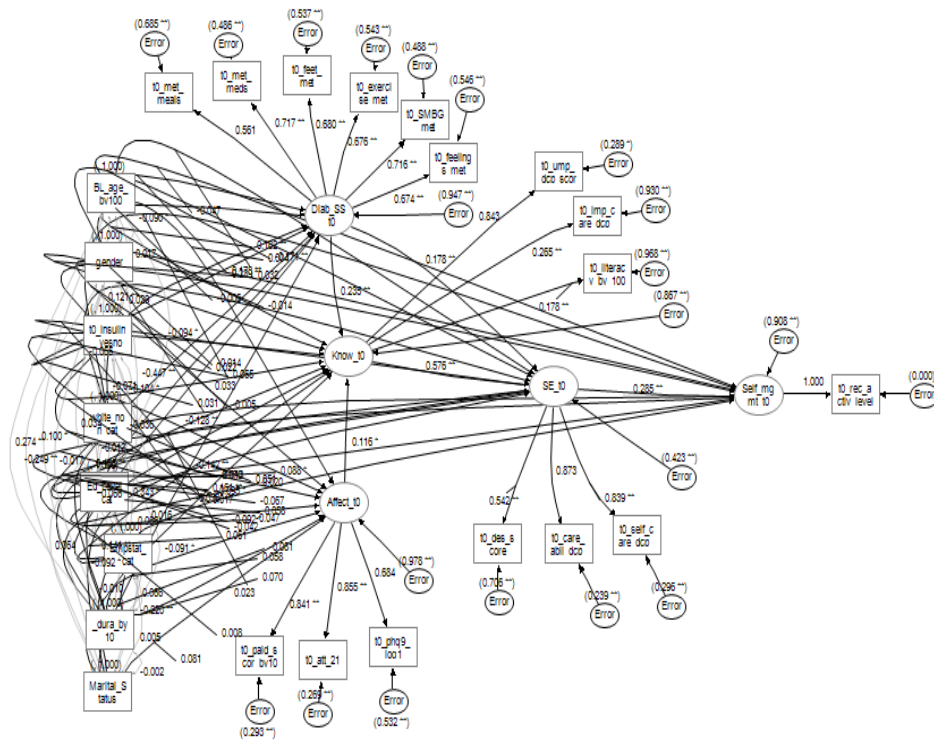
Fit Summary

Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	386.7178
	Chi-Square DF	188
	Pr > Chi-Square	<.0001
Parsimony Index	Standardized RMR (SRMR)	0.0438
	Adjusted GFI (AGFI)	0.9141
	Parsimonious GFI	0.6445
	RMSEA Estimate	0.0433
	RMSEA Lower 90% Confidence Limit	0.0372
	RMSEA Upper 90% Confidence Limit	0.0495
	Probability of Close Fit	0.9636
Incremental Index	Bentler Comparative Fit Index	0.9392

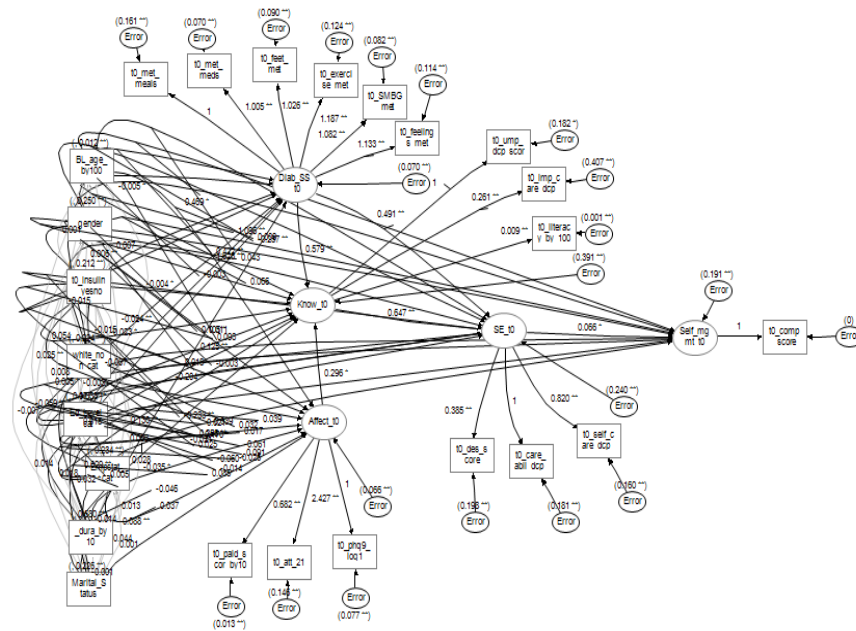
TO FINAL RESPEC – DIET STD



TO FINAL RESPEC- EXERCISE STD



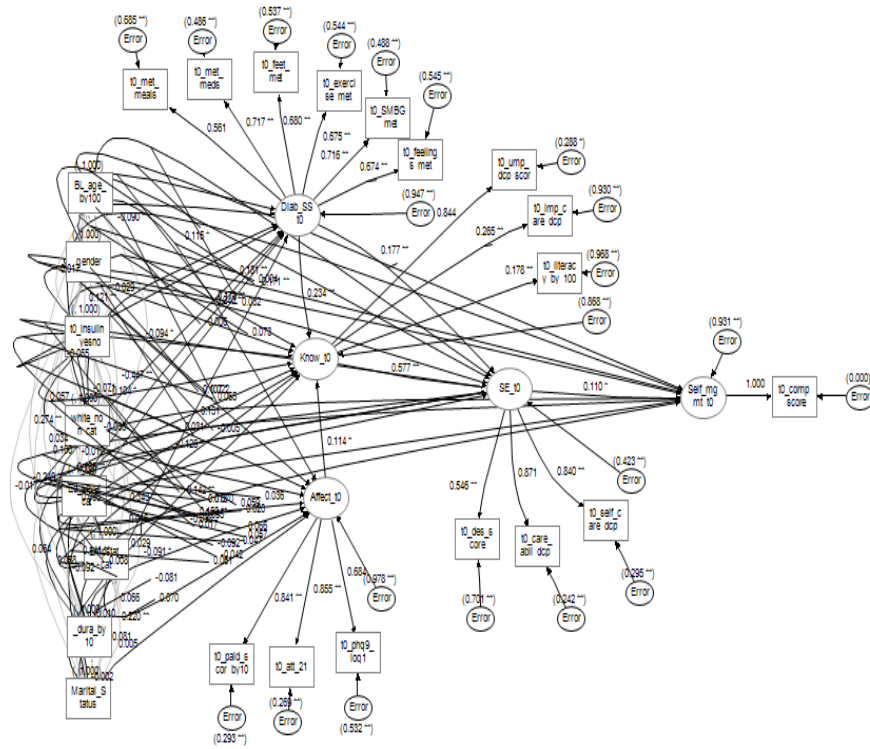
TO FINAL RESPEC – COMPETENCY UNSTD



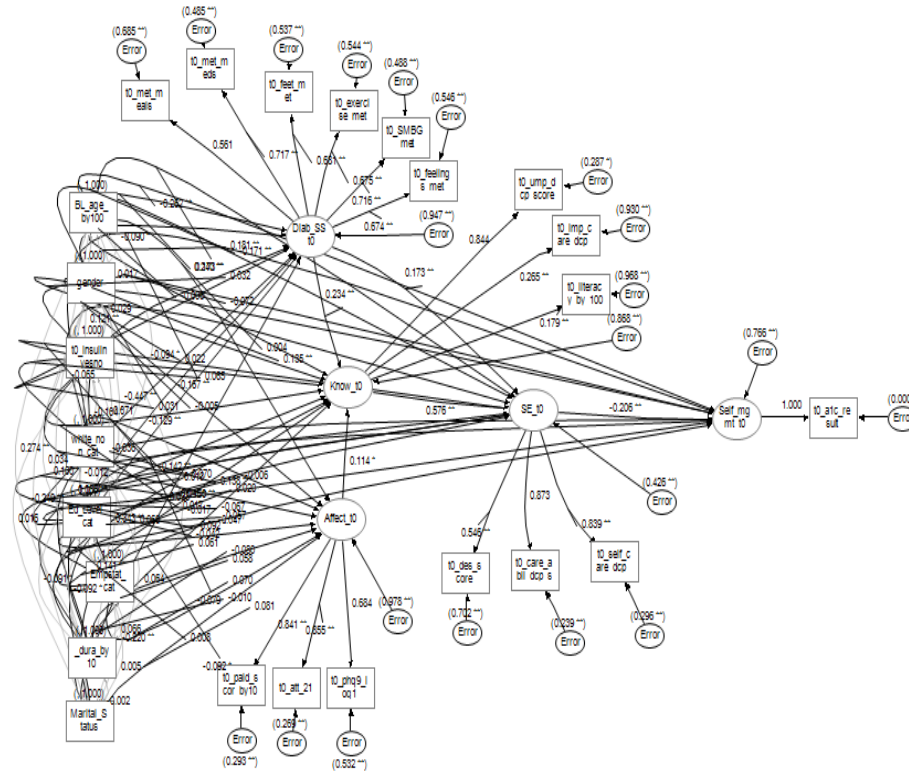
Fit Summary

Modeling Info	Number of Observations	564
	Chi-Square	384.1713
Absolute Index	Chi-Square DF	188
	Pr > Chi-Square	<.0001
Parsimony Index	Standardized RMR (SRMR)	0.0438
	Adjusted GFI (AGFI)	0.9139
	Parsimonious GFI	0.6444
	RMSEA Estimate	0.0431
	RMSEA Lower 90% Confidence Limit	0.0369
	RMSEA Upper 90% Confidence Limit	0.0492
	Probability of Close Fit	0.9691
Incremental Index	Bentler Comparative Fit Index	0.9399

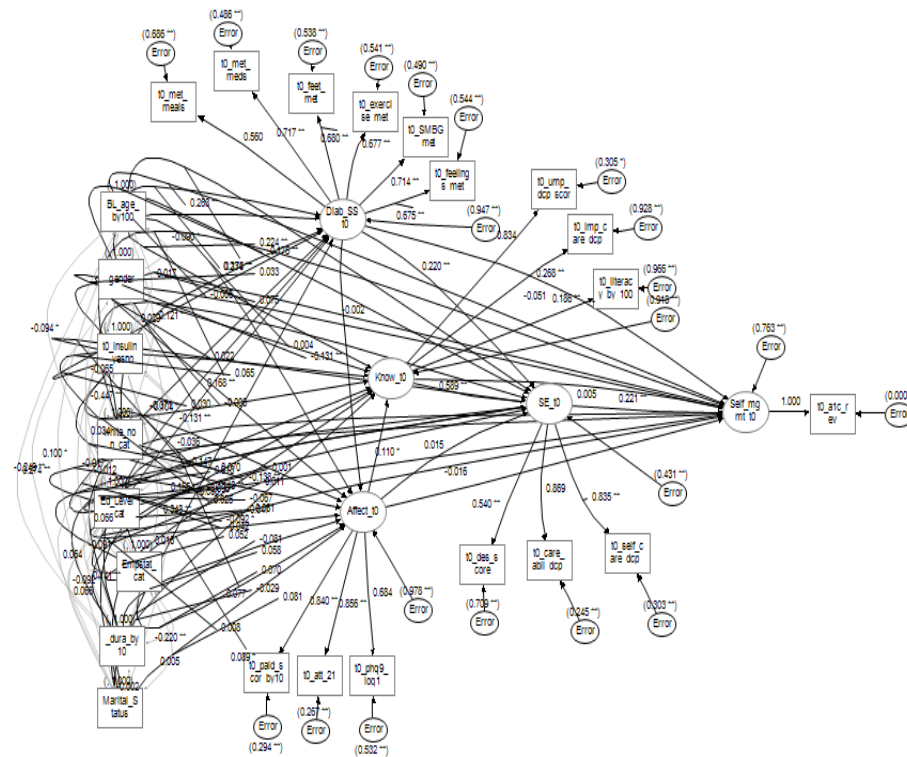
TO FINAL RESPEC- COMPETENCY STD



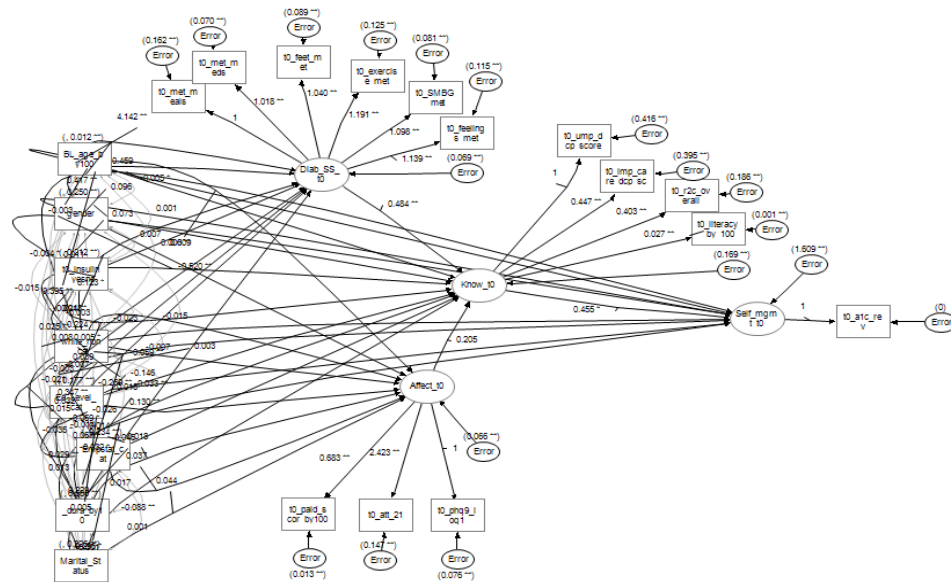
TO FINAL RESPEC- A1C STD



TO Model 3 Original STD



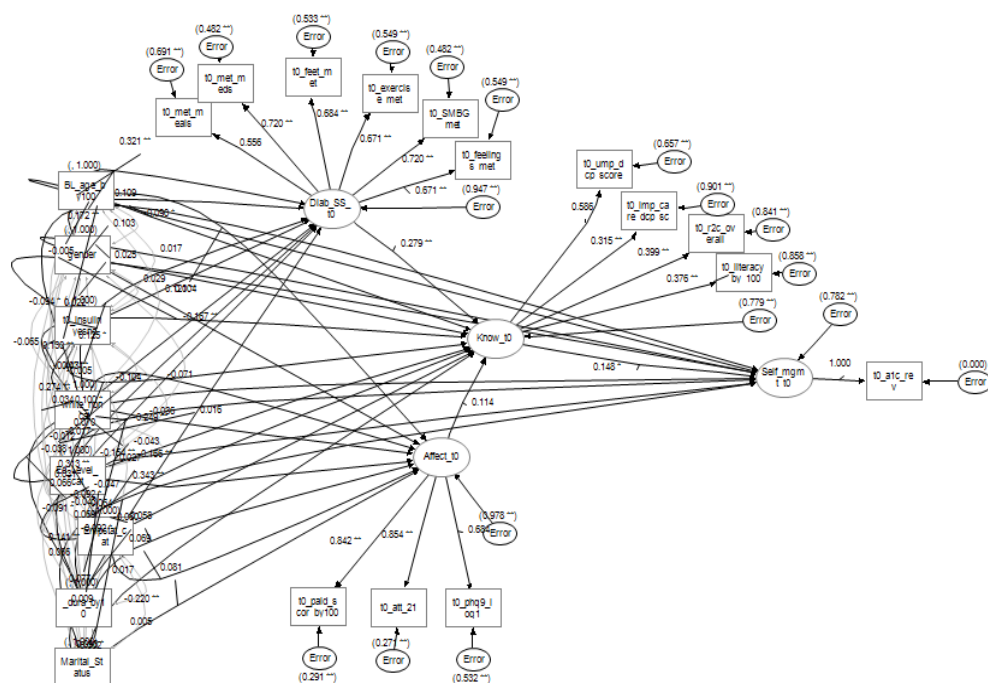
EQUIV 2 MODEL – NO SE UNSTD



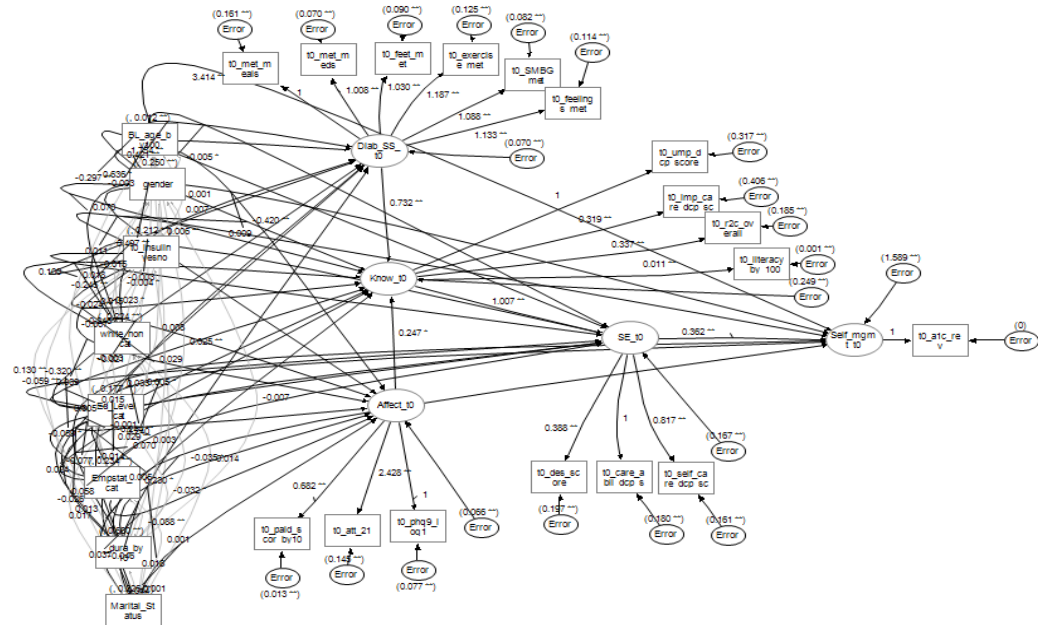
Fit Summary

Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	314.6494
	Chi-Square DF	155
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0424
Parsimony Index	Adjusted GFI (AGFI)	0.9219
	Parsimonious GFI	0.6389
	RMSEA Estimate	0.0428
	RMSEA Lower 90% Confidence Limit	0.0360
	RMSEA Upper 90% Confidence Limit	0.0495
	Probability of Close Fit	0.9606
Incremental Index	Bentler Comparative Fit Index	0.9361

EQUIV 2 MODEL – NO SE



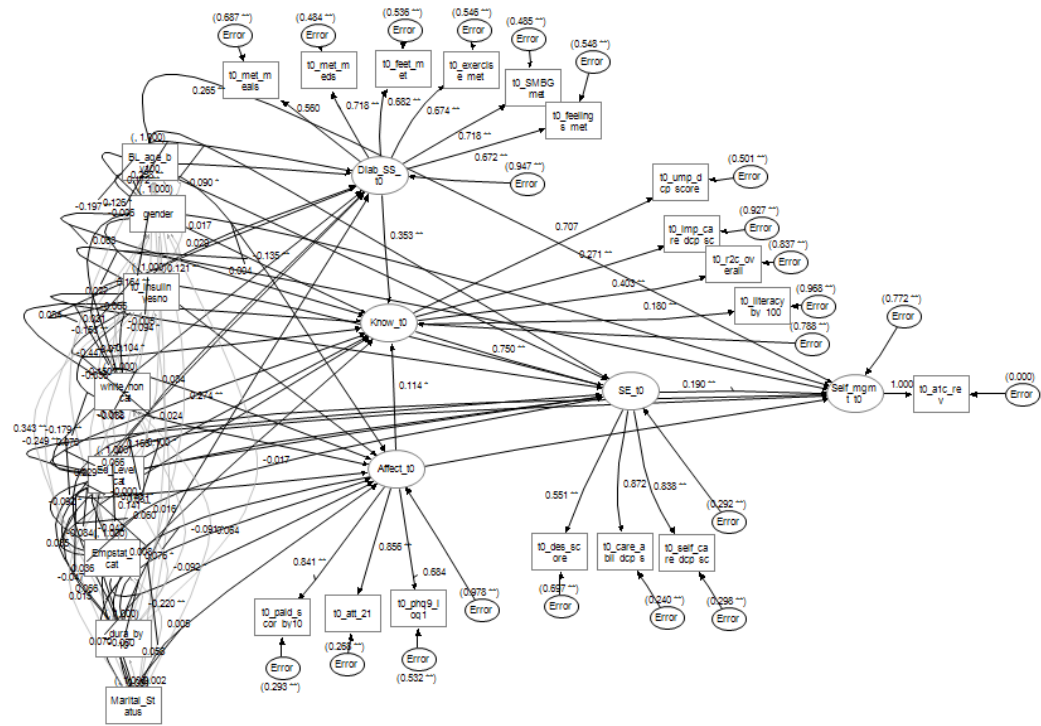
EQUIV 3 MODEL UNSTD – KNOW as Mediator for DSS and AFFECT



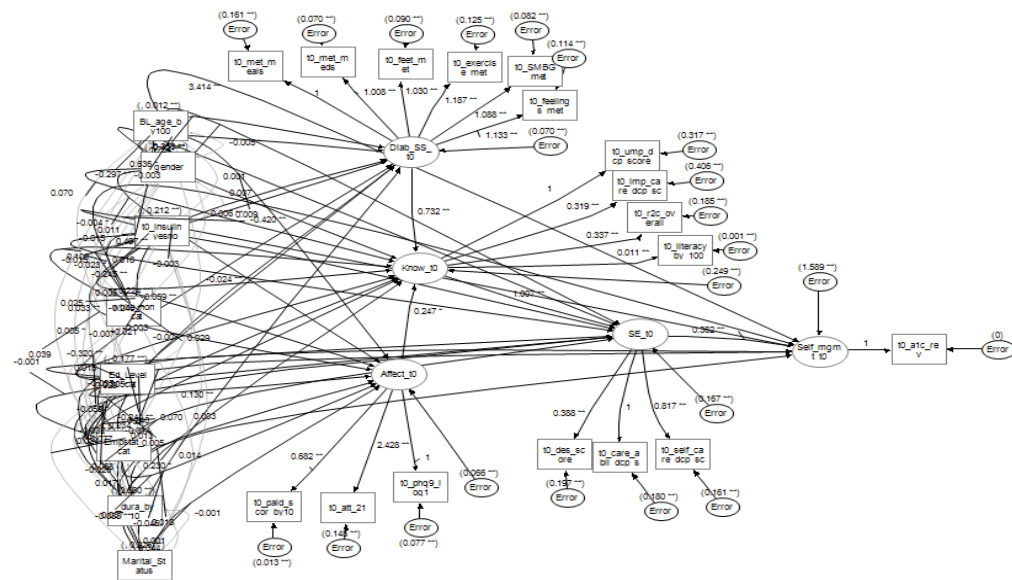
Fit Summary

Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	436.3368
	Chi-Square DF	214
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0451
Parsimony Index	Adjusted GFI (AGFI)	0.9126
	Parsimonious GFI	0.6723
	RMSEA Estimate	0.0430
	RMSEA Lower 90% Confidence Limit	0.0372
	RMSEA Upper 90% Confidence Limit	0.0487
	Probability of Close Fit	0.9784
Incremental Index	Bentler Comparative Fit Index	0.9356

EQUIV 3 MODEL – STD



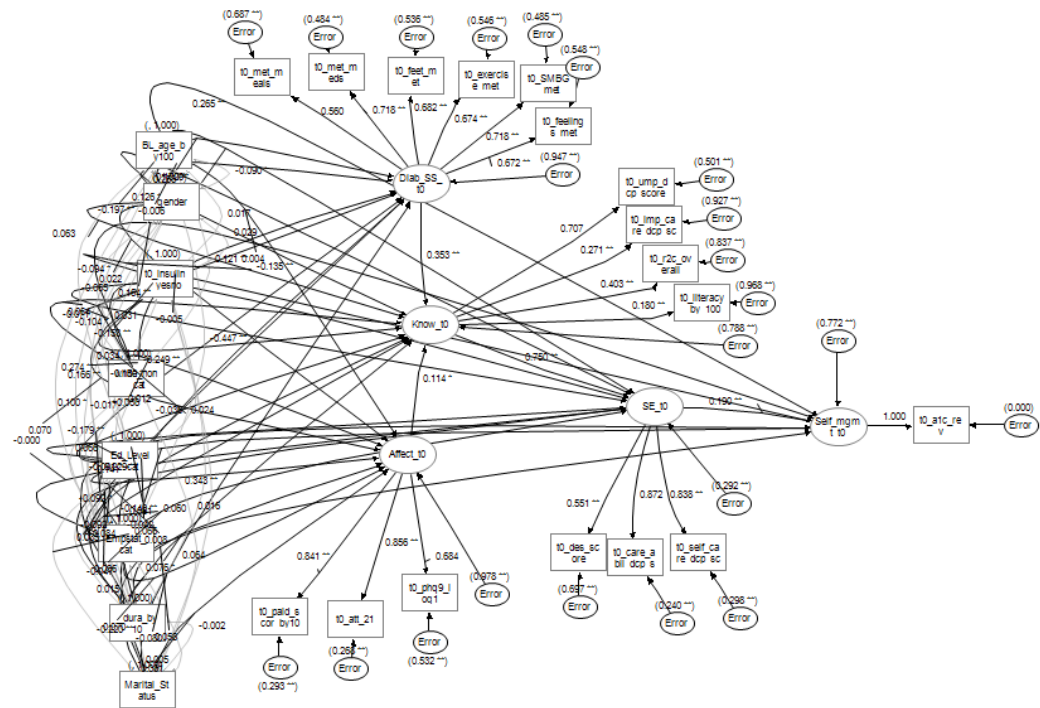
Model 2 EQUIVALENT– UNSTD Know and SE as mediators with A1c



Fit Summary

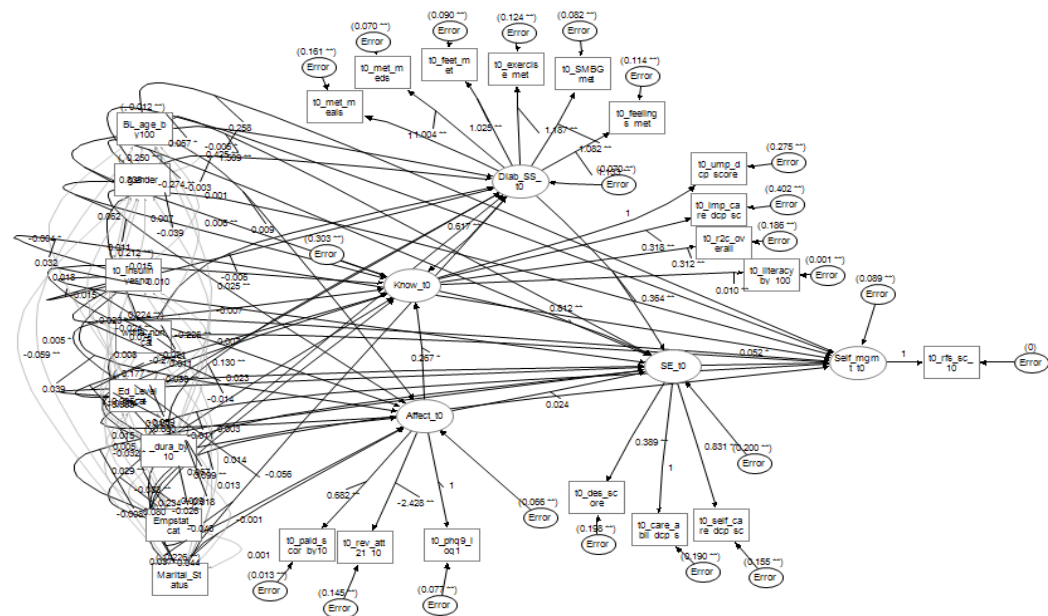
Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	436.3368
	Chi-Square DF	214
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0451
Parsimony Index	Adjusted GFI (AGFI)	0.9126
	Parsimonious GFI	0.6723
	RMSEA Estimate	0.0430
	RMSEA Lower 90% Confidence Limit	0.0372
	RMSEA Upper 90% Confidence Limit	0.0487
	Probability of Close Fit	0.9784
Incremental Index	Bentler Comparative Fit Index	0.9356

EQUIVALENT MODEL 2 STD



Model 3 Equivalent UNSTD

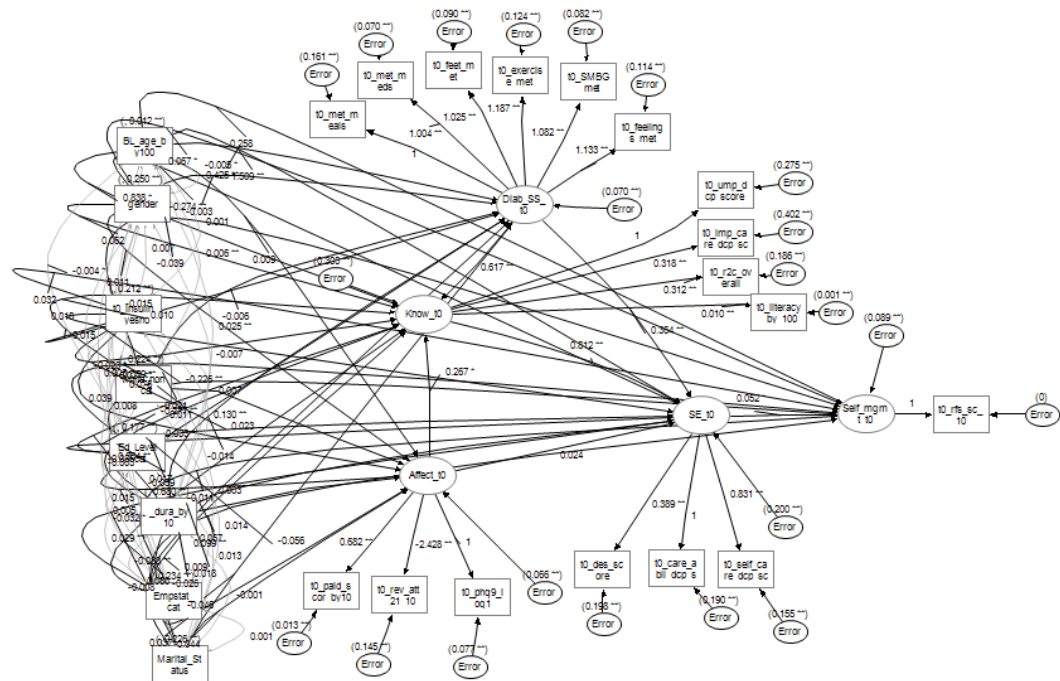
(RFS with all to SE and DSS and AFFECT TO KNOW) STD



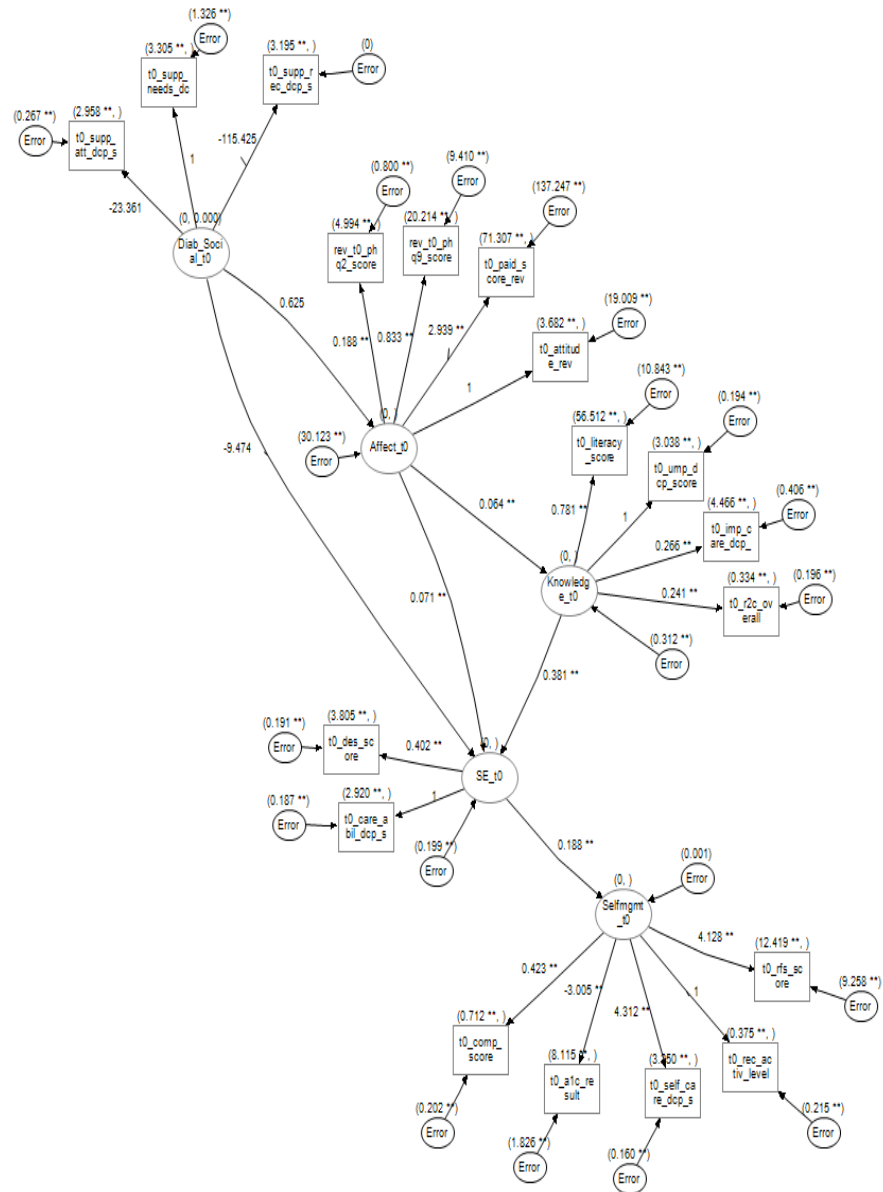
Fit Summary

Modeling Info	Number of Observations	564
Absolute Index	Chi-Square	448.5476
	Chi-Square DF	211
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0448
Parsimony Index	Adjusted GFI (AGFI)	0.9083
	Parsimonious GFI	0.6614
	RMSEA Estimate	0.0447
	RMSEA Lower 90% Confidence Limit	0.0390
	RMSEA Upper 90% Confidence Limit	0.0505
	Probability of Close Fit	0.9346
Incremental Index	Bentler Comparative Fit Index	0.9292

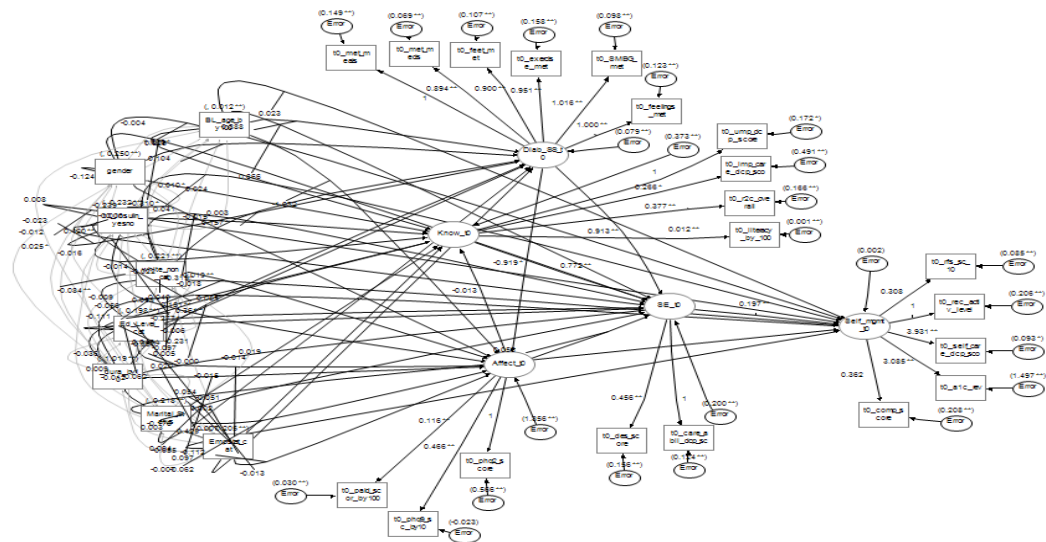
MODEL 3 Equivalent – STD



TO 564 RAW DATA - FULL MODEL FIML QN 5000 (WORKING)



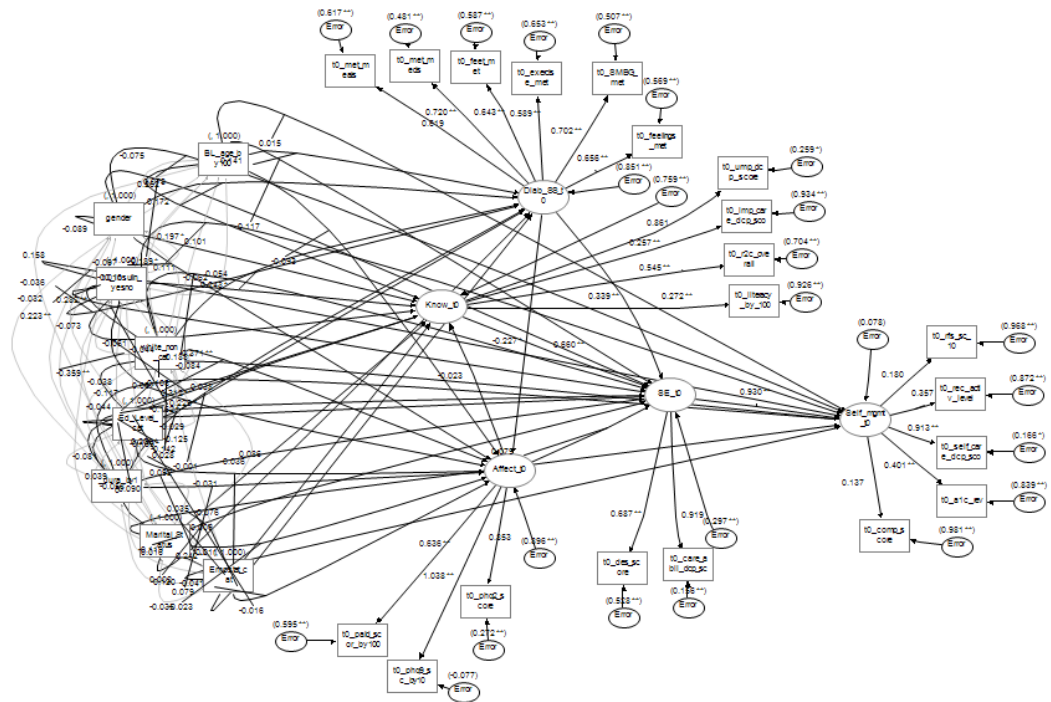
T0 GROUP 0 = USUAL CARE - UNSTD



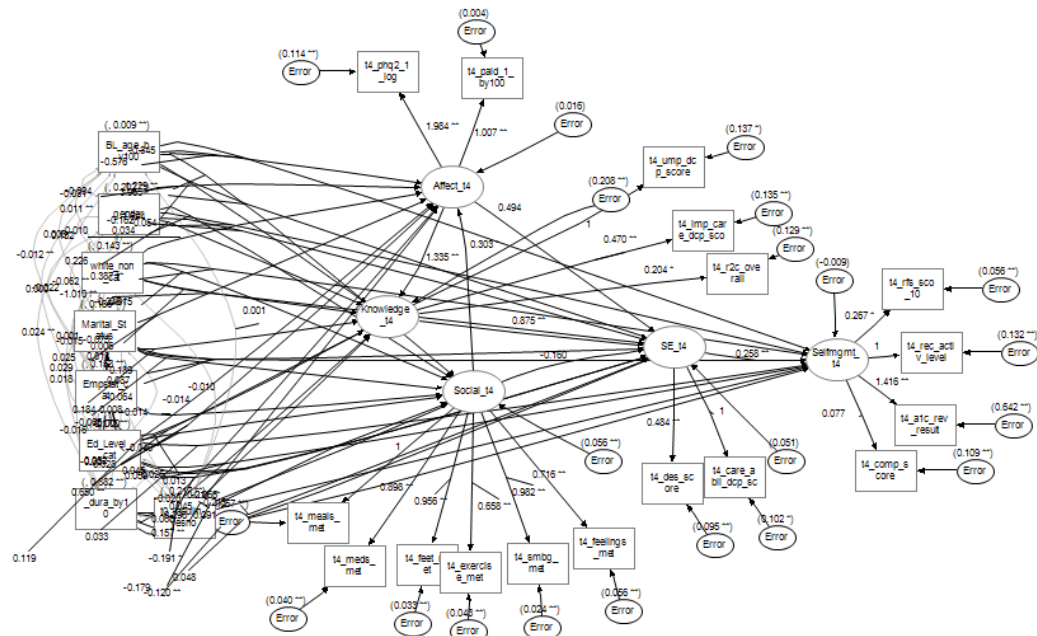
Fit Summary

Modeling Info	Number of Observations	123
Absolute Index	Chi-Square	410.7818
	Chi-Square DF	284
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0783
Parsimony Index	Adjusted GFI (AGFI)	0.7444
	Parsimonious GFI	0.6170
	RMSEA Estimate	0.0605
	RMSEA Lower 90% Confidence Limit	0.0471
	RMSEA Upper 90% Confidence Limit	0.0730
	Probability of Close Fit	0.0950
Incremental Index	Bentler Comparative Fit Index	0.8764

TO Group 0 = USUAL CARE - STD



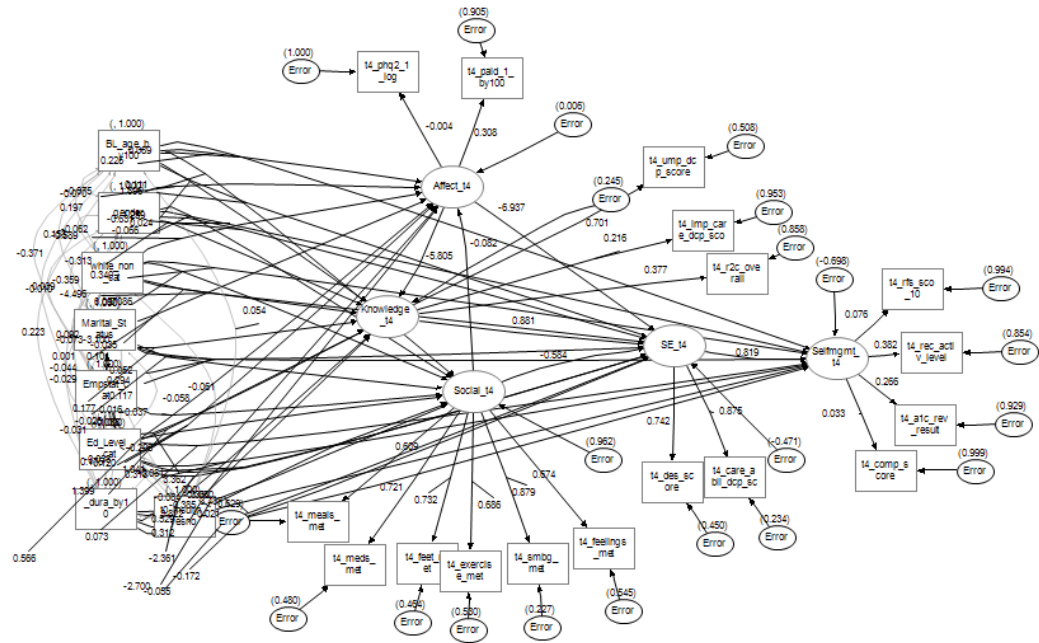
T4 Usual Care –UNSTD GLS



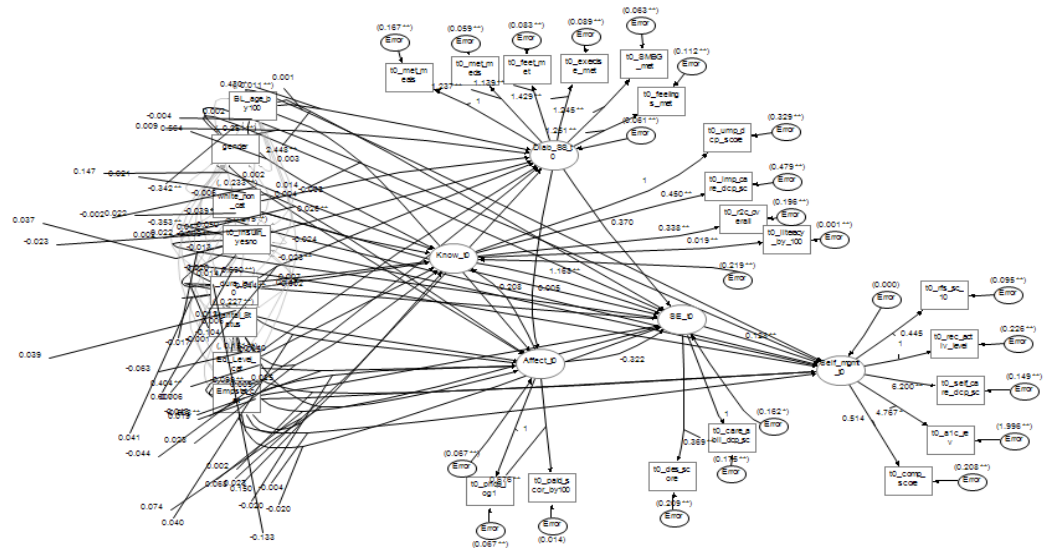
Fit Summary

Modeling Info	Number of Observations	123
Absolute Index	Chi-Square	260.6440
	Chi-Square DF	208
	Pr > Chi-Square	0.0077
	Standardized RMR (SRMR)	0.1335
Parsimony Index	Adjusted GFI (AGFI)	0.7329
	Parsimonious GFI	0.5748
	RMSEA Estimate	0.0455
	RMSEA Lower 90% Confidence Limit	0.0247
	RMSEA Upper 90% Confidence Limit	0.0621
	Probability of Close Fit	0.6524
Incremental Index	Bentler Comparative Fit Index	0.7199

T4 USUAL CARE STD



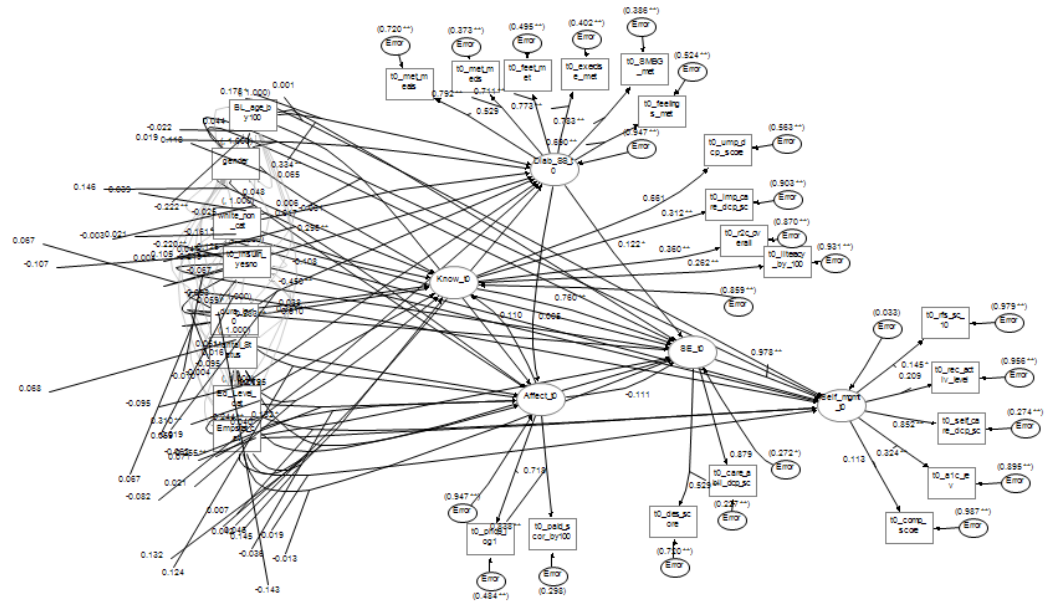
T0 ED GROUP 1 – UNSTD



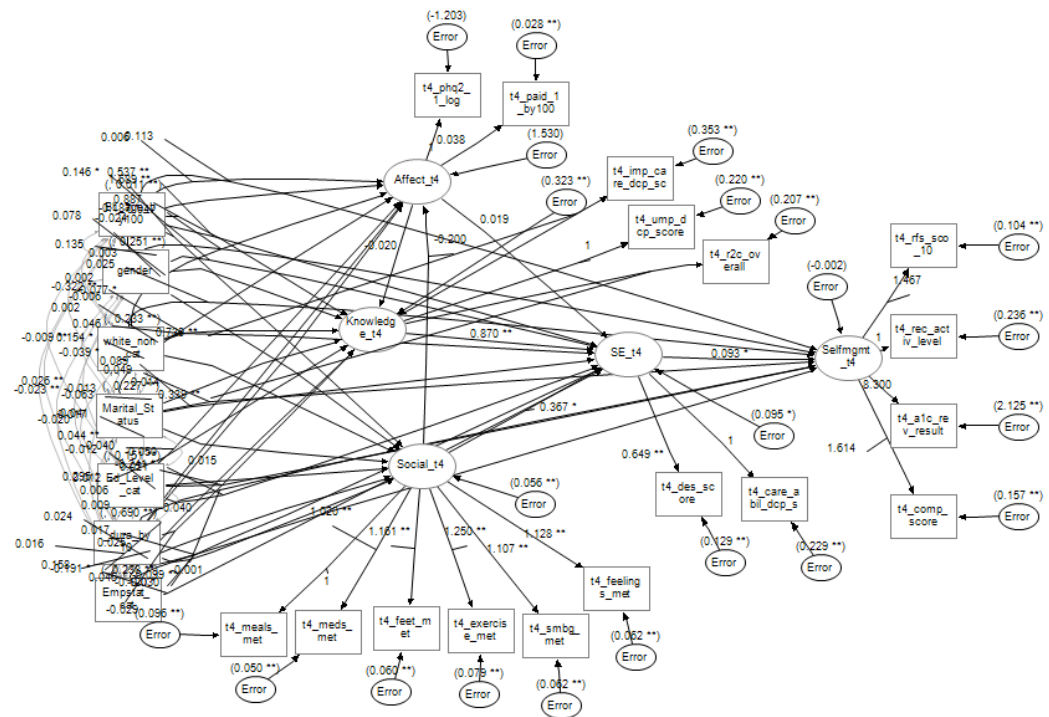
Fit Summary

Modeling Info	Number of Observations	219
Absolute Index	Chi-Square	511.2794
	Chi-Square DF	258
	Pr > Chi-Square	<.0001
Parsimony Index	Standardized RMR (SRMR)	0.0767
	Adjusted GFI (AGFI)	0.7927
	Parsimonious GFI	0.6311
	RMSEA Estimate	0.0671
	RMSEA Lower 90% Confidence Limit	0.0586
	RMSEA Upper 90% Confidence Limit	0.0756
	Probability of Close Fit	0.0007
Incremental Index	Bentler Comparative Fit Index	0.8203

TO ED GROUP 1 – STD



T4 ED GROUP 1 – UNSTD

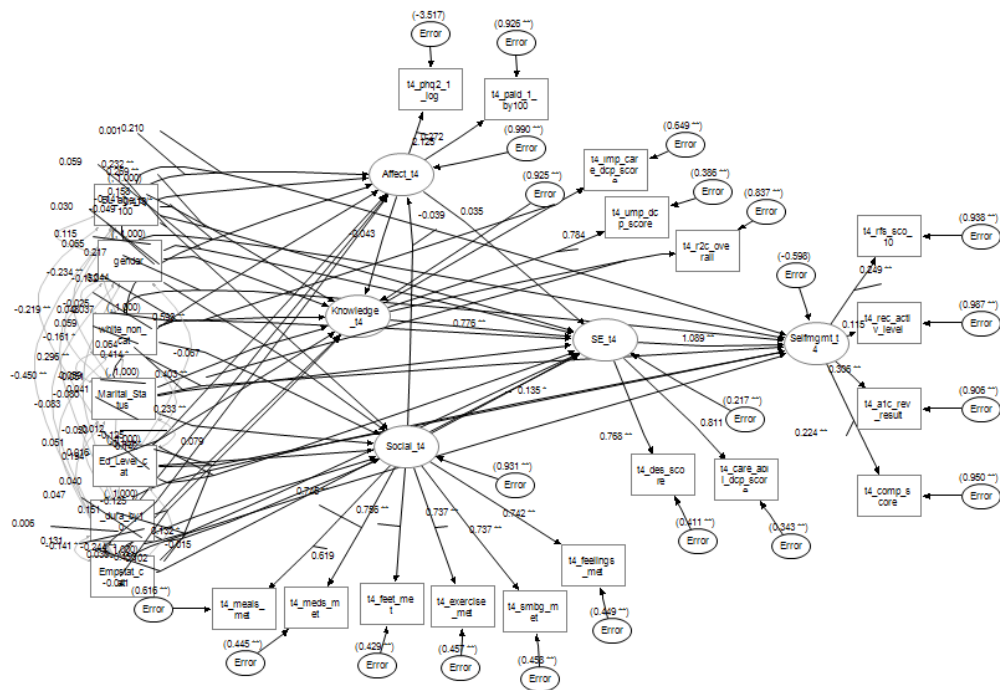


Fit

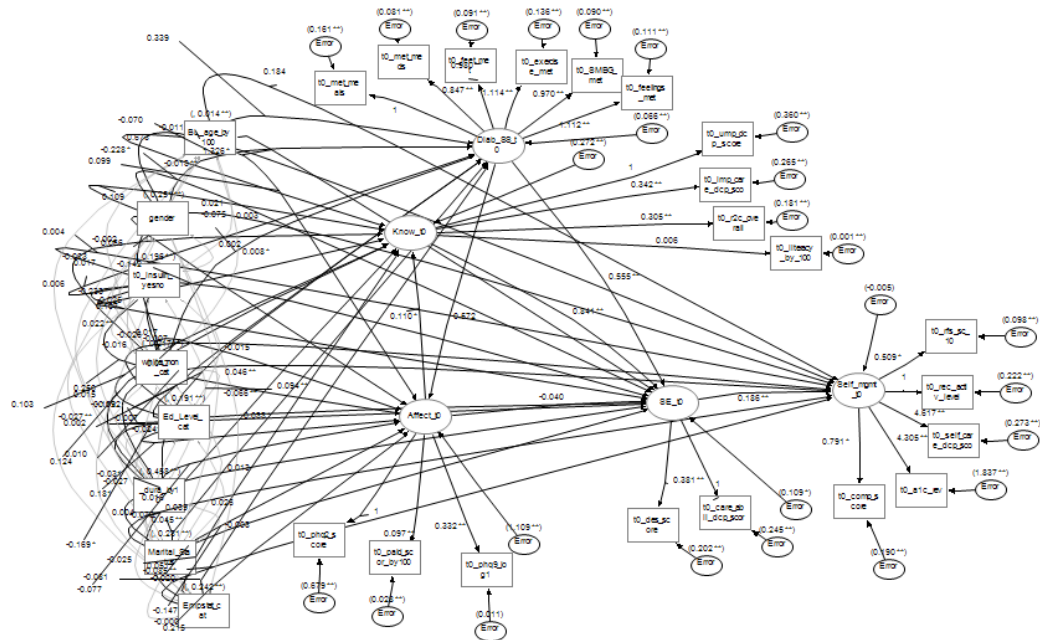
Fit Summary

Modeling Info	Number of Observations	219
Absolute Index	Chi-Square	325.6098
	Chi-Square DF	197
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0556
Parsimony Index	Adjusted GFI (AGFI)	0.8337
	Parsimonious GFI	0.6358
	RMSEA Estimate	0.0547
	RMSEA Lower 90% Confidence Limit	0.0439
	RMSEA Upper 90% Confidence Limit	0.0651
	Probability of Close Fit	0.2255
Incremental Index	Bentler Comparative Fit Index	0.8951

T4 ED GROUP 1 – STRD



T0 ED GROUP 2–UNSTD

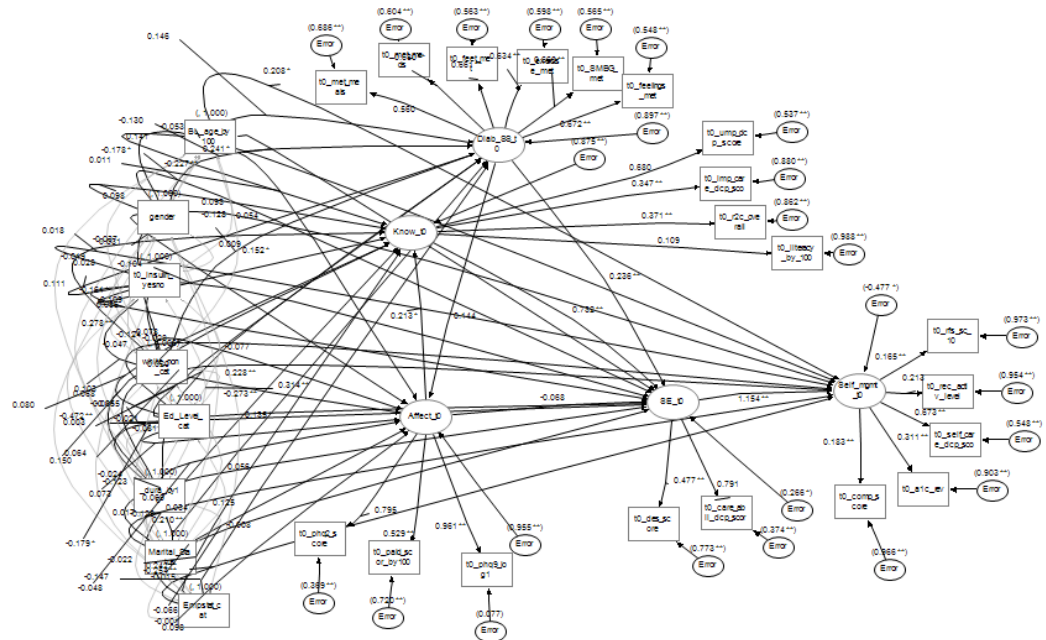


Fit

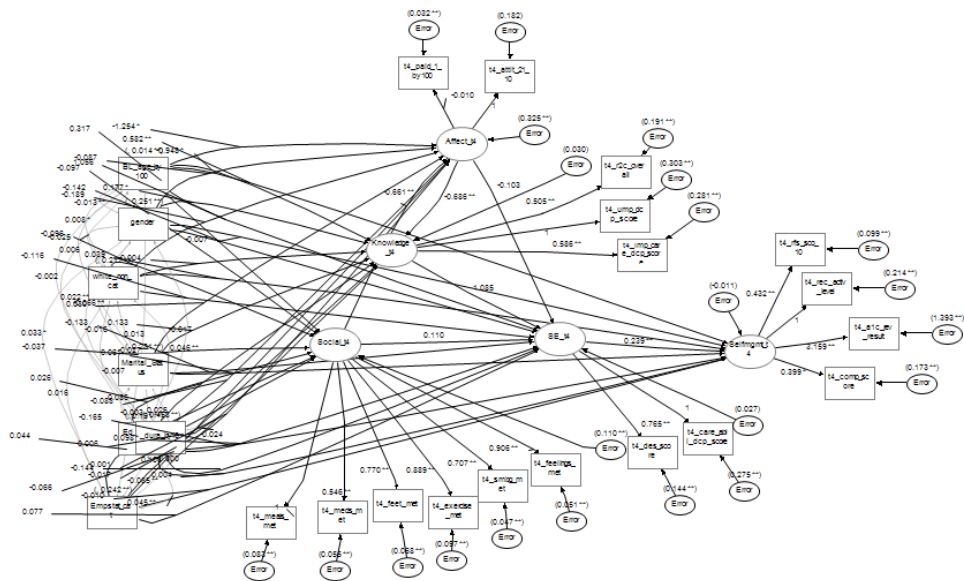
Fit Summary

Modeling Info	Number of Observations	222
Absolute Index	Chi-Square	452.7182
	Chi-Square DF	284
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0655
Parsimony Index	Adjusted GFI (AGFI)	0.8213
	Parsimonious GFI	0.6574
	RMSEA Estimate	0.0518
	RMSEA Lower 90% Confidence Limit	0.0427
	RMSEA Upper 90% Confidence Limit	0.0606
	Probability of Close Fit	0.3583
Incremental Index	Bentler Comparative Fit Index	0.8660

T0 ED GROUP 2-STD



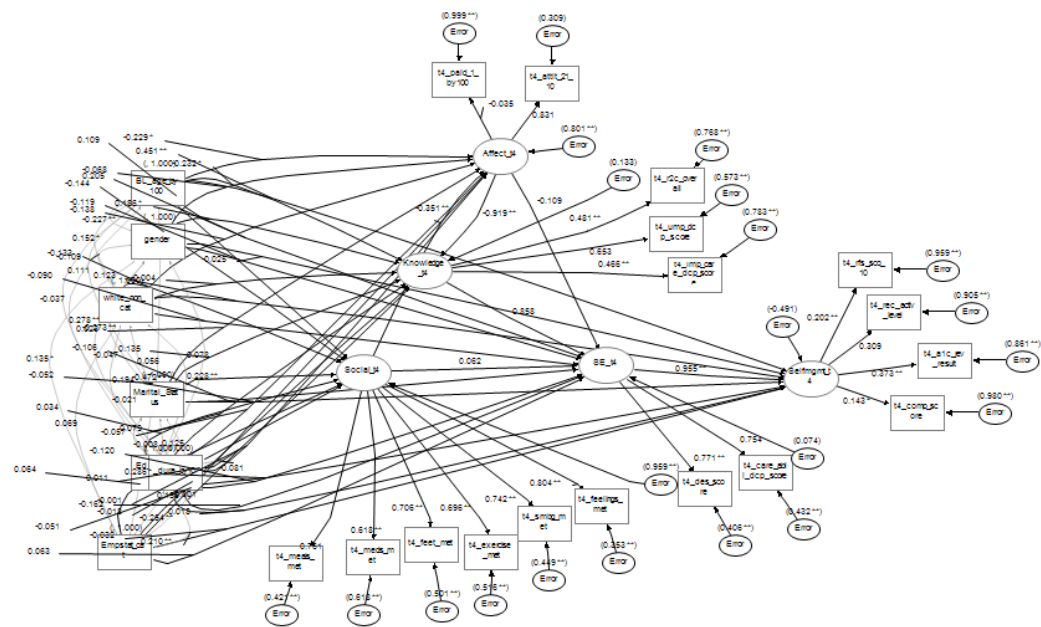
T4 ED GROUP 2 – UNSTD



Fit Summary

Modeling Info	Number of Observations	222
Absolute Index	Chi-Square	299.8531
	Chi-Square DF	197
	Pr > Chi-Square	<.0001
	Standardized RMR (SRMR)	0.0586
Parsimony Index	Adjusted GFI (AGFI)	0.8436
	Parsimonious GFI	0.6405
	RMSEA Estimate	0.0486
	RMSEA Lower 90% Confidence Limit	0.0372
	RMSEA Upper 90% Confidence Limit	0.0594
	Probability of Close Fit	0.5714
Incremental Index	Bentler Comparative Fit Index	0.9175

T4 STD ED GROUP 2



APPENDIX C***PROC CALIS SEM CODE:***

```

path
9092    Affect_t4      <- _dura_by10      ,
9093    Affect_t4      <- BL_age_by100      ,
9094    Affect_t4      <- Ed_Level_cat      ,
9095    Affect_t4      <- gender          ,
9096    Affect_t4      <- Marital_Status    ,
9097    Affect_t4      <- Social_t4        ,
9098    Affect_t4      <- t0_BMI_by_100      ,
9099    Affect_t4      <- t0_insulin_yesno  ,
9100    Affect_t4      <- white_non_cat    ,
9101    Knowledge_t4   <- _dura_by10      ,
9102    Knowledge_t4   <- Affect_t4        ,
9103    Knowledge_t4   <- BL_age_by100      ,
9104    Knowledge_t4   <- Ed_Level_cat      ,
9105    Knowledge_t4   <- gender          ,
9106    Knowledge_t4   <- Marital_Status    ,
9107    Knowledge_t4   <- t0_BMI_by_100      ,
9108    Knowledge_t4   <- t0_insulin_yesno  ,
9109    Knowledge_t4   <- white_non_cat    ,
9110    SE_t4           <- _dura_by10      ,
9111    SE_t4           <- Affect_t4        ,
9112    SE_t4           <- BL_age_by100      ,
9113    SE_t4           <- Ed_Level_cat      ,
9114    SE_t4           <- gender          ,
9115    SE_t4           <- Knowledge_t4      ,
9116    SE_t4           <- Marital_Status    ,
9117    SE_t4           <- Social_t4        ,
9118    SE_t4           <- t0_BMI_by_100      ,
9119    SE_t4           <- t0_insulin_yesno  ,
9120    SE_t4           <- white_non_cat    ,
9121    Selfmgmt_t4     <- _dura_by10      ,
9122    Selfmgmt_t4     <- BL_age_by100      ,
9123    Selfmgmt_t4     <- Ed_Level_cat      ,
9124    Selfmgmt_t4     <- gender          ,
9125    Selfmgmt_t4     <- Marital_Status    ,
9126    Selfmgmt_t4     <- SE_t4          ,
9127    Selfmgmt_t4     <- t0_BMI_by_100      ,
9128    Selfmgmt_t4     <- t0_insulin_yesno  ,
9129    Selfmgmt_t4     <- white_non_cat    ,
9130    Social_t4       <- _dura_by10      ,
9131    Social_t4       <- BL_age_by100      ,
9132    Social_t4       <- Ed_Level_cat      ,
9133    Social_t4       <- gender          ,
9134    Social_t4       <- Marital_Status    ,
9135    Social_t4       <- t0_BMI_by_100      ,
9136    Social_t4       <- t0_insulin_yesno  ,

```

```

9137     Social_t4      <- white_non_cat    ,
9138     t4_a1c_rev_result <- Selfmgmt_t4    ,
9139     t4_attit__20_by10 <- Affect_t4      = 1,
9140     t4_care_abil_dcp_score <- SE_t4      = 1,
9141     t4_comp_score      <- Selfmgmt_t4    ,
9142     t4_des_score       <- SE_t4          ,
9143     t4_exercise_met     <- Social_t4     ,
9144     t4_feelings_met     <- Social_t4     ,
9145     t4_feet_met        <- Social_t4     ,
9146     t4_imp_care_dcp_score <- Knowledge_t4 ,
9147     t4_meals_met        <- Social_t4     = 1,
9148     t4_meds_met         <- Social_t4     ,
9149     t4_paid_by100       <- Affect_t4     ,
9150     t4_phq2_score       <- Affect_t4     ,
9151     t4_r2c_overall      <- Knowledge_t4  ,
9152     t4_rec_activ_level  <- Selfmgmt_t4   = 1,
9153     t4_rfs_sco_10       <- Selfmgmt_t4   ,
9154     t4_smbg_met         <- Social_t4     ,
9155     t4_ump_dcp_score    <- Knowledge_t4   = 1
9156 ;
9157 pcov
9158     _dura_by10    BL_age_by100    ,
9159     _dura_by10    Ed_Level_cat    ,
9160     _dura_by10    gender          ,
9161     _dura_by10    Marital_Status  ,
9162     _dura_by10    t0_BMI_by_100   ,
9163     _dura_by10    t0_insulin_yesno ,
9164     _dura_by10    white_non_cat   ,
9165     BL_age_by100  Ed_Level_cat    ,
9166     BL_age_by100  gender          ,
9167     BL_age_by100  Marital_Status  ,
9168     BL_age_by100  t0_BMI_by_100   ,
9169     BL_age_by100  t0_insulin_yesno ,
9170     BL_age_by100  white_non_cat   ,
9171     Ed_Level_cat  gender          ,
9172     Ed_Level_cat  Marital_Status  ,
9173     Ed_Level_cat  t0_BMI_by_100   ,
9174     Ed_Level_cat  t0_insulin_yesno ,
9175     Ed_Level_cat  white_non_cat   ,
9176     gender        Marital_Status  ,
9177     gender        t0_BMI_by_100   ,
9178     gender        t0_insulin_yesno ,
9179     gender        white_non_cat   ,
9180     Marital_Status t0_BMI_by_100   ,
9181     Marital_Status t0_insulin_yesno ,
9182     Marital_Status white_non_cat   ,
9183     t0_BMI_by_100 t0_insulin_yesno ,
9184     t0_BMI_by_100 white_non_cat   ,
9185     t0_insulin_yesno white_non_cat

```